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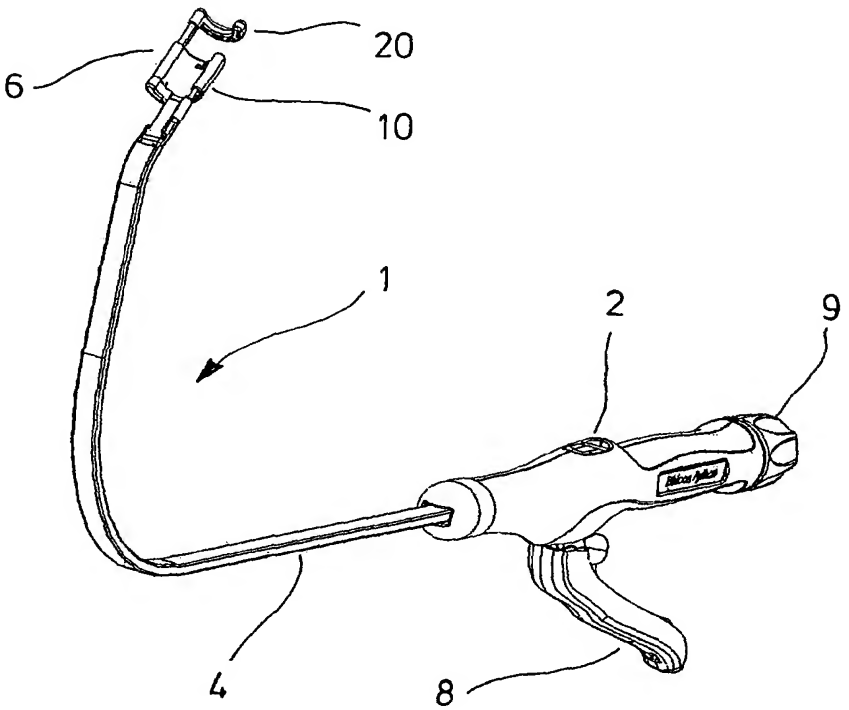
(54) Title: SURGICAL SYSTEM WITH A STAPLING INSTRUMENT AND A RETRACTOR




(57) Abstract: In a surgical system, a stapling instrument (1) comprises a flexible shaft device (4), a handle (2), and a staple fastening assembly (6). The staple fastening assembly (6) includes a curved cartridge (10), which comprises at least one curved open row of staples, and, opposite to the cartridge (10), a curved anvil (20), which has a staple forming face and is adapted to cooperate with the cartridge (10) for forming the ends of the staples exiting from the cartridge (10). Preferably, the staple fastening assembly (6) is adapted to allow unobstructed access towards concave inner faces of the cartridge (10) and of the anvil (20). The anvil (20) can be moved relatively with respect to the cartridge (109, from a spaced position for positioning tissue therebetween to a closed position for clamping the tissue. The surgical system further includes a retractor adapted to draw tissue into the space between the cartridge (10) and the anvil (20), when the cartridge (10) and the anvil (20) are in the spaced position. In a preferred application, the surgical system is used in the treatment of gastroesophageal reflux desease (GERD).

WO 2004/110285 A1

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

# Surgical system with a stapling instrument and a retractor

The invention relates to a surgical system with a stapling instrument and a retractor and can be used, e.g., in the treatment of gastric reflux.

Gastroesophageal reflux desease (GERD) is widely spread. For example, in the United States of America, 7% of the adult population suffers from the symptoms associated therewith, like heartburn and regurgitations. Complications include Barrett esophagus, adenocarcinoma and, generally, a low quality of life. Whereas in most cases a pharmaceutical therapy with antisecretory agents is applied, in about 15% of the cases a surgical therapy is indicated.

In the Nissen technique (see, e.g., R. Nissen et al., "20 years in the management of reflux disease using fundoplication", Chirurg **48**: 10, 634-9, Oct. 1977), the esophagus is fully or partially surrounded by the stomach wall at the greater curvature of the stomach to create a more effective lower esophageal sphincter (LES) valve. This surgery is performed endoscopically or via an open access. The complication rate, however, is relatively high. For example, 5% of the patients suffer from dysphagia, a constriction of the lower esophagus. And on the long term, more than 50% of the patients have to take antisecretory agents again.

Endoscopic techniques involve a transoral access via the esophagus. In the Stretta procedure (see, e.g., G. Ilopoulos et al., "The Stretta procedure for the treatment of GERD: 6 and 12 month

follow-up of the U.S. open label trial", Gastrointest. Endosc. 55: 2, 149-56, Feb. 2002), RF energy is used to create a smooth muscle lesion of the lower esophageal sphincter and the cardia. This lesion heals causing tissue contraction to increase the effectiveness of the LES valve. Up to now, little is known about long-term complications and the occurence of disphagia.

In another endoscopic technique, by means of the apparatus disclosed in WO 00/78227 A1, a plication with serosa-to-serosa opposition is sutured within 1 cm of the gastro-esophageal junction to increase the effectiveness of the LES valve. This results in a small reduction of the esophageal diameter, and again, little is known about long-term complications and the occurence of disphagia.

Another endoscopic procedure (see, e.g. *http://www.ndosurgical.com/pages/procedure.html*), in which a submucosal plication is created at the gastro-esophageal junction to increase the valve effectiveness, takes about one hour to perform, which is rather long. In this case, long term studies (including studies of disphagia) are missing as well.

WO 01/91646 A1 discloses a surgical stapling instrument comprising a body portion with a rigid shaft, a handle and a staple fastening assembly. The staple fastening assembly includes a curved cartridge, which comprises at least one curved open row of staples, and a curved anvil, which is adapted to cooperate with the cartridge for forming the ends of the staples exiting from the cartridge. The staple fastening assembly is adapted to allow unobstructed access towards the concave inner faces of the cartridge and the anvil. The cartridge can be moved towards the anvil from a spaced position for positioning tissue therebetween to a closed position for clamping the tissue. Preferably, a knife is contained within the cartridge and is positioned such that there is at least one row of staples on at least one side of the knife. This instrument is particularly useful for the

treatment of a patient's rectum, e.g., in order to resect a polyp.

It is the object of the invention to provide a surgical possibility, in particular for a safe and effective transoral therapy of gastroesophageal reflux desease which principally excludes the occurence of disphagia.

This object is achieved by a surgical system having the features of claim 1. The other claims define advantageous embodiments of that system as well as components thereof.

The surgical system according to the invention includes a stapling instrument and a retractor.

The stapling instrument comprises a flexible shaft device, a handle extending from the shaft device in the proximal end region of the stapling instrument as well as a staple fastening assembly in the distal end region of the stapling instrument. Here and in the following, the terms "proximal" and "distal" relate to the user as reference, which means that the parts of the instrument close to the user under normal operating conditions are designated as "proximal". The term "shaft devive" is to be understood in a broad sense. Generally, the shaft device connects the handle with the staple fastening assembly, and the shaft device can include adapter members, connectors, etc., and its cross-sectional shape can vary along its length.

The staple fastening assembly includes a curved cartridge, which comprises at least one curved open row of staples, and, opposite to the cartridge, a curved anvil, which has a staple forming face and is adapted to cooperate with the cartridge for forming the ends of the staples exiting from the cartridge. A moving device is adapted to move the anvil relatively with respect to the cartridge, essentially in parallel relationship, from a spaced position for positioning tissue therebetween to a closed

position for clamping the tissue. A staple driving device is adapted to drive the staples out of the cartridge towards the anvil. Preferably, the staple fastening assembly is adapted to allow unobstructed access towards concave inner faces of the cartridge and of the anvil.

Preferably, the staple forming face of the anvil is generally planar and is arranged transversally (preferably orthogonally) with respect to the longitudinal axis of the staple fastening assembly. However, different geometries are conceivable as well, e.g. curved or undulated shapes of the staple forming face, depending on the desired shape of the arrangement of the staples in the tissue of a patient, and even when the staple forming face of the anvil is planar it need not be orthogonal with respect to the longitudinal axis of the staple fastening assembly.

Herein, the term "cartridge" is used in the general sense of "staple magazine". Thus, it is not restricted to a removable component of the staple fastening assembly, although in a preferred embodiment the cartridge is removable such that it can be replaced by a fresh one, if additional staples are needed during a surgical procedure.

Moreover, the term "staple" is used in a very general sense. It includes metal staples or clips, but also surgical fasteners made of synthetic material and similar fasteners. Synthetic fasteners usually have a counterpart (retainer member) held at the anvil. In this sense, the terms "anvil" and "staple forming plane" also have a broad meaning which includes, in the case of two-part synthetic fasteners, the anvil-like tool and its plane where the retainer members are held, and similar devices.

The retractor of the surgical system according to the invention is adapted to draw tissue into the space between the cartridge and the anvil, when the cartridge and the anvil are in the spaced position. The retractor can be an instrument separate from

the stapling instrument. Alternatively, the retractor is integrated in the stapling instrument. In the latter case, preferably, the retractor is operated via actuating members located at or in the proximity of the handle.

Preferably, the surgical system according to the invention is used with an endoscope. The endoscope can have a working channel, for example for guiding the retractor in case the retractor is a separate instrument. The endoscope can be a component of the surgical system.

In a preferred application, the surgical system according to the invention is used in the transoral therapy of gastroesophageal reflux desease. In this case, the endoscope is a steerable endoscope adapted to be inserted through the esophagus as far as into the stomach. Such an endoscope is known in the art and is called a gastroscope.

Generally, the surgical procedure preferably is performed in the following way: First the gastroscope is orally introduced into the stomach, where it is moved in retrograde state viewing the Z line. If the retractor is a separate instrument, it is introduced via the working channel of the gastroscope until it contacts the anterior mucosal wall, about 3 cm below the Z line. There, the stomach tissue is "grasped" (see below for an example) by the retractor, and traction is applied by means of the retractor until a full thickness transversal fold of stomach tissue is formed. While the traction is maintained, the stapling instrument is orally introduced alongside the gastroscope, i.e. outside the gastroscope and using the gastroscope as exterior guide, to the site of the fold. Under retrograde view with the gastroscope, the stapling instrument, with the cartridge and the anvil in the spaced position, is positioned in such a way that the transversal fold is located in the space between the cartridge and the anvil. Then, the anvil is moved relatively to the cartridge in order to clamp the tissue, and the stapling instru-

ment is activated to drive the staples out of the cartridge towards the anvil, thus stapling the fold in place to create a permanent protrusion below the lower esophageal sphincter. If desired, another fold is stapled on the posterior wall, i.e. opposite to the first fold, by means of the same instruments. Afterwards, the stapling instrument and the retractor are extracted. After checking whether the fold(s) are correct and close off the esophagus, the gastroscope can be extracted as well.

The order of some of the steps of this surgical procedure can be changed, if desired. For example, the stapling instrument may be introduced first, and afterwards the retractor is moved to the site below the lower esophageal sphincter to draw tissue into the space between the cartridge and the anvil, when the cartridge and the anvil are in the spaced position.

If the retractor is integrated in the stapling instrument, the procedure is similar, but there is no need to insert and remove the retracting and stapling tools independently. A detailed example is presented below.

In both cases, the result of the surgery is one or two permanent folds in the form of generally transversal protrusions below the lower esophageal sphincter. The folds permit food to enter the stomach without problems. Concerning gastric reflux, however, they form a kind of barriers which influence the gastric circulation in a beneficial way, thus avoiding or at least largely reducing a reflux from the stomach into the esophagus. The problem of disphagia does not occur because the lower esophagus is not affected by this surgical technique. In particular, the lower esophagus is not constricted. Consequently, by means of the surgical system according to the invention, gastroesophageal reflux desease can be cured in an efficient manner.

A major advantage of preferred embodiments of the stapling instrument is the shape of the staple fastening assembly which allows tissue stapling through unobstructed access and unobstructed vision. Because of the free access towards concave inner faces of the cartridge and of the anvil, the retractor can be used easily, effectively and safely. Moreover, the stapling instrument can be arranged alongside a gastroscope in a space-saving manner.

Preferably, the outer faces of the cartridge and the anvil are ergonomically shaped to match the anatomy at the site of the surgical procedure. The cartridge and the anvil can have a generally arc-like shape in the cross-sectional plane, the arc extending over an angle in the range 90° to 350°.

In an advantageous version, the anvil is supported by means of at least one arm extending from an end of the anvil and generally running in parallel to the longitudinal axis of the staple fastening assembly. This arm does not interfere with the retractor and does not block the surgeon's view. Preferably, the moving device is connected to the arm in order to move the anvil with respect to the cartridge. The staple fastening assembly can include a curved holder which is adapted to accomodate the cartridge, and the holder can comprise a guide adapted to slidably guiding the arm. Preferably, the shape of the holder is arc-like in the cross-sectional plane and is similar to that of the cartridge and the anvil, allowing an unobstructed access towards the concave inner face of the holder as well. A staple fastening assembly designed in this way greatly facilitates the surgical applications of the instrument.

The distance between the cartridge and the anvil in the closed position is preferably adjustable. For example, the moving device can comprise an adjustable stop (preferably operated by elements located at the handle) in order to prevent the anvil from

moving beyond the stop position and from clamping the tissue too much, thus avoiding necrosis.

In an advantageous version of the invention, the staple fastening assembly comprises a retaining pin adapted to move, preferably to slide, between the cartridge and the anvil to align the cartridge and the anvil. Preferably, the movement of the retaining pin is actuateable via an actuating member located at the handle. The retaining pin provides an additional support for the anvil and can be useful when other supports like the arm mentioned above, for reasons of limited space, cannot be dimensioned so large that they prevent a misalignment due to elastic deformation.

Preferably, the staple driving device is adapted to simultaneously drive the staples out of the cartridge towards the anvil.

In an advantageous version of the invention, the flexible shaft device comprises a plurality of vertebra members, which are longitudinally arranged and are surrounded by a flexible sheath. Preferably, each of the vertebra members has at least one opening, the openings of the longitudinally arranged vertebra members forming at least one channel adapted to accomodate force transmitting devices for transmitting forces from actuating members located at the handle to the staple fastening assembly. Such force transmitting devices can include, e.g., a flexible band associated to the moving device and a flexible band associated to the staple driving device and also additional devices, in particular for operating the retaining pin (see above) and for operating movable parts of a retractor which is integrated in the stapling instrument (see below).

The staple fastening assembly can be removably mounted in the distal end region of the flexible shaft device. This allows the flexible shaft device and many parts of the moving device, the staple driving device and force transmitting devices to be desi-

gned as re-usable components, which are sterilized after each surgical procedure, whereas the staple fastening assembly can be replaced after each surgical procedure.

As already mentioned, the cartridge is preferably removable so that a used cartridge without staples can be replaced with a fresh one, if required. This is particularly advantageous if the stapling instrument is to be used several times during the same surgical procedure. It is also conceivable to design the stapling instrument as a re-usable instrument which is sterilized after each surgical procedure. In this case, a fresh and sterile cartridge can be inserted during the next surgical procedure.

In case the retractor is an instrument separate from the stapling instrument, in an advantageous version the retractor comprises a screw which is adapted to pierce and to be screwed into tissue and which is mounted at one end of a flexible retractor shaft. Preferably, the screw is designed as a coil. This retractor is used by piercing the tissue at the position where it is to be "gripped" by means of the tip of the screw and then rotating the flexible retractor shaft by a few full turns such that the screw or coil is screwed into the tissue, thus anchoring the retractor in the tissue. Afterwards, the tissue can be drawn, e.g. to the shape of a fold, by pulling at the retractor shaft. After stapling the fold, the screw is rotated in the opposite direction in order to separate it from the tissue. If the tissue in question is the stomach wall, piercing it with the retractor does not seriously hurt the patient.

In an advantageous design in which the retractor is integrated in the stapling instrument, the retractor comprises a hollow needle with an internal channel and an expandable balloon, which is adapted to be pushed out of the piercing tip of the needle via the channel. The needle can be designed as a curved needle. The balloon can be mounted on a catheter. Preferably, the needle is slidably mounted in a retractor sheath having a proximal end

and a distal end, wherein the needle can be moved out of the distal end region of the retractor sheath by means of a force transmitter operated via the proximal end region of the retractor sheath. The retractor sheath can be movable, generally in parallel to the longitudinal axis of the staple fastening assembly. When using this retractor, the needle tip is exposed from the protective retractor sheath, the tissue is pierced by means of the needle (at the position where it is to be "gripped"), and then the balloon is moved out of the channel of the needle and inflated. Afterwards, the tissue can be retracted by drawing at the retractor, the inflated balloon preventing the needle from slipping out off the tissue. The details of this procedure are explained below.

Whereas the preferred embodiment of the screw/coil-type retractor is a separate instrument and the preferred embodiment of the needle/balloon-type retractor is an integrated tool of the stapling instrument, it is also conceivable to integrate a screw/-coil-type retractor in the stapling instrument or to design a needle/balloon-type retractor as a separate instrument.

In the following, the invention and its application in the surgical treatment of gastroesophageal reflux desease are further described by means of embodiments. The drawings show in

Figure 1 an isometric overall view of the stapling instrument of a first embodiment of the surgical system according to the invention,

Figure 2 a side view of the stapling instrument of Figure 1,

Figure 3 in parts (a) and (b) isometric views of the staple fastening assembly of the stapling instrument of Figure 1 from two different directions,

Figure 4 an isometric view similar to Figure 3 (a), but with the cartridge of the staple fastening assembly unlokked and partly pulled out of its holder,

Figure 5 an isomentric view of the cartridge of the staple fastening assembly of Figure 3,

Figure 6 an isometric view of the anvil of the staple fastening assembly of Figure 3,

Figure 7 in parts (a), (b) and (c) sequential steps in actuating the staple fastening assembly of Figure 3, which illustrates how the staples are expelled from the cartridge and are formed,

Figure 8 an exploded view of the staple fastening assembly of Figure 3,

Figure 9 an isometric view of vertebra members forming the backbone of the flexible shaft of the stapling instrument of Figure 1,

Figure 10 a schematic isometric view showing the proximal end region of the flexible shaft of the stapling instrument of Figure 1,

Figure 11 a schematic isometric view showing the distal end region of the flexible shaft of the stapling instrument of Figure 1,

Figure 12 in parts (a), (b) and (c) sequential steps in actuating the stapling instrument, like in Figure 7, but in longitudinal section,

Figure 13 a schematic view of the stomach of a patient with a gastroscop introduced through the esophagus,

Figure 14 in parts (a), (b), (c) and (d) schematic views of sequential steps of a surgical procedure for the treatment of gastroesophageal reflux desease,

Figure 15 an isometric view of the distal area of the retractor of the first embodiment of the surgical system according to the invention,

Figure 16 a side view of the distal area of the retractor of Figure 15,

Figure 17 in parts (a), (b), (c), (d) and (e) schematic views of sequential steps of the use of the retractor of Figure 15,

Figure 18 in parts (a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k) and (l) side views, partially in longitudinal section, of the staple fastening assembly of the stapling instrument and of the retractor of a second embodiment of the surgical system according to the invention, illustrating, in sequential steps, how this embodiment is used in a surgical procedure for the treatment of gastroesophageal reflux desease, and

Figure 19 the fold of the the stomach wall created in the procedure illustrated in Figure 18, i.e. in part (a) in longitudinal side view, also illustrating the staples set in the procedure, and in part (b) in top view.

In a first embodiment of the surgical system, a stapling instrument and a retractor are designed as separate components. This embodiment is illustrated by means of Figures 1 to 17.

Figure 1 shows an isometric view of the stapling instrument, whereas Figure 2 is a side elevational view. The stapling instrument 1 comprises a handle 2 in the proximal area of the

instrument, a flexible shaft 4, and a staple fastening assembly 6 mounted at the distal end of the shaft 4. A trigger 8 and a rotatable knob 9 provided at the handle 2 can be used in order to operate the staple fastening assembly 6, as explained below in more detail.

In the embodiment, the stapling instrument 1 is designed for the use in a surgical procedure for the treatment of gastroesophageal reflux desease (GERD). Thus, the staple fastening assembly 6 is dimensioned such than it can be introduced through the mouth and the esophagus of the patient into the stomach, and the flexible shaft 4 is somewhat longer than the esophagus. In use, the handle 2 is outside the mouth of the patient such that the actuating members (like the trigger 8 and the knob 9) can be conveniently operated by the surgeon.

The stapling instrument 1 is designed as a disposable instrument. A stapling instrument which is completely sterilizable or partly sterilizable (for example with a sterilizable handle only or with sterilizable shaft and handle) is conceiveable as well.

Figures 3 to 7 illustrate the staple fastening assembly 6 in more detail.

A curved cartridge 10 containing staples is removably mounted in a curved holder 12. The cartridge 10 is secured by means of a protrusion 14 and a bayonet slot 15 in the holder 12, see in particular Figure 3 (a) and Figure 4.

An end face 16 of the cartridge 10 is provided with slots 18. In the embodiment, four slots 18 are arranged along a semi-circular line. Each slot houses a staple (clip) with the free ends pointing to the end face 16 (see Figure 7 (b) and additionnally Figures 8 and 12). Thus, the slots 18 define a curved open row of staples.

Opposite to the cartridge 10, the staple fastening assembly 6 comprises a curved anvil 20 having an atraumatically shaped distal face 22 and a staple forming face 24 which is aligned in parallel to the end face 16 of cartrige 10. The staple forming face 24 is provided with depressions 25, see Figure 6. The depressions 25 are arranged in pairs, and each pair serves to bend the free ends of one staple expelled from the cartridge 10, see in particular Figure 7 (c) and Figure 12 (c).

The anvil 20 is supported by an arm 26 extending from one end of the anvil 20 and running in parallel to the longitudinal axis of the staple fastening assembly 6. The opposite end of the anvil 20 is the free end 27. The arm 26 is slidably guided in a guide 28 formed at one end of the holder 12, the cross-sectional area of the guide 28 being adapted to that of the arm 26. As explained in more detail below, the anvil 20 can be moved via the arm 26 towards the cartridge 10 to a closed position for clamping tissue and away from the cartridge 10 to a spaced position. In the embodiment, the distance between the cartridge 10 and the anvil 20 in the closed position (i.e. the gap shown in Figures 7 and 12) is adjustable by means located at the handle 2.

Figures 3, 4, 7, and 8 display a retaining pin 30 as an additional part of the staple fastening assembly 6. The retaining pin 30 has a shaft 32, a rounded or somewhat tapered distal end 34, and a proximal end region 35 with a larger diameter than shaft 32.

The retaining pin 30 is slidably guided in a bore 36 provided at one end of cartridge 10. The purpose of the retaining pin 30 is to aid in the alignment of the anvil 20 with respect to the cartridge 10 and the holder 12. Since the dimensions of the staple fastening assembly 6 are small, the arm 26 might not be strong enough to prevent the free end 27 of the anvil 20 from misalignment. In use, the retaining pin 30 is slidably moved in distal direction until its distal end 34 fits into a recess 39 provided

close to the free end 27 of the anvil 20, see Figure 6. The shape of the recess 39 is adapted to that of the distal end 34 of the retaining pin 30 such that the anvil 20 automatically aligns to the cartridge 10 when the distal end 34 of the retaining pin 30 moves into the recess 39. A correct alignment is important in order to form the ends of the staples in a precise way.

Whereas the anvil 20 is actively moved by driving the arm 26, the retaining pin 30 passively slides in the bore 36, when the anvil 20 approaches the cartridge 10. In order to position the retaining pin 30 with its distal end 34 resting in the recess 39, a kind of Bowden wire is used which is not illustrated in the figures. The Bowden wire acts onto the proximal end region 35 of the retaining pin 30 and is operated from the handle 2.

Figure 8 is an exploded view of the staple fastening assembly 6. The four staples housed in the cartridge 10 are designated by 40. The shaft 4 ends with a rigid distal shaft part 42 to which two holder parts 44 and 45 are screwed, as indicated by the auxiliary lines in Figure 8. When assembled, the holder parts 44 and 45 form the holder 12 including the guide 28.

The distal end 46 of a flexible band 47 and the distal end 48 of a flexible band 49 are shown in Figure 8. The flexible bands 47 and 49 are guided in a longitudinal channel inside the distal shaft part 42 and along the flexible shaft 4, see also Figures 10, 11 and 12. A base part 50 of the anvil 20 is screwed to the distal end 46 of the flexible band 47. The flexible band 47 can be longitudinally moved inside the shaft 4 by rotating knob 9 at the handle 2. In this way, the moving device is formed which moves the anvil 20 with respect to the cartridge 10.

A pusher base 52 is screwed to the distal end 48 of flexible band 49. The flexible band 49 can be longitudinally moved inside the shaft 4, independently from the flexible band 47, by means

of the trigger 8 provided at the handle 2. When the trigger 8 is actuated, i.e. drawn towards the rigid part of handle 2, the flexible band 49 and the pusher base 52 are shifted in distal direction. Therefore, the pusher base 52 acts onto a driver part 54 which is a component of the replacable cartridge 10. The driver part 54 includes fingers 56, one for each staple 40, which expell the staples 40 from the slots 18 during this "firing" actuation. These steps are also illustrated in Figures 7 and 12, where parts (a) show the initial condition with the desired gap between the anvil 20 and the cartridge 10, parts (b) display the moment when the free ends of the staples 40 touch the depressions 25 in the staple forming face 24 of the anvil 20, and parts (c) show the final state with the ends of the staples formed (bent).

The "backbone" of the flexible shaft 4 is illustrated in Figure 9. It consists of a plurality of vertebra members 60 which are longitudinally arranged. In the embodiment, each of the vertebra members 60 has one opening, the openings of the longitudinally arranged vertebra members 60 forming a channel 62 of rectangular cross-sectional shape. The flexible bands 47 and 49 are guided inside channel 62, see Figure 10, which shows the proximal end region of shaft 4 (without handle 2), and Figure 11, which shows the distal end region of shaft 4. Figures 10 and 11 also illustrate a flexible sheath 64 which surrounds the vertebra members 60.

The rigid vertebra members 60 abute each other. Thus, the array of vertebra members 60 can transmit compression forces counteracting tensil forces transmitted via the flexible band 47. The flexible sheath 64 provides flexibility to the shaft 4 and is also able to transmit tensil forces when the flexible band 49 is exposed to compression forces during the firing of the staples. Since the cross-sections of the channel 62 is adapted to the combined cross section of the flexible bands 47 and 49, the bands 47 and 49 can transmit compression forces although they

are flexible. Because of the shape of the vertebra members 60, the flexible shaft 4 displays flexibility in one direction only (i.e. within one plane), as indicated in Figures 1, 2 and 9.

Mechanisms for transmitting forces and actions from actuating members like the trigger 8 or the knob 9 are generally known in the art, see, e.g., US Patent 5 605 272 and US Patent 4 527 724.

A surgical procedure for the treatment of gastroesophageal reflux desease by using a surgical system comprising the stapling instrument described above and a retractor is generally illustrated in Figures 13 and 14.

Figure 13 shows a schematic cross section through the stomach 70 of a patient. The esophagus 72 enters into the upper part of the stomach 70. In its lower part, the stomach 70 is connected to the duodenum 74. In the view of Figure 13, a conventional gastroscop 80 has been introduced through the mouth of the patient and the esophagus 72 into the stomach 70. The gastroscop 80 is an endoscope including optics and has a steerable end region 82 which can be bent up to 180°, as shown in Figure 13.

Figure 14, in parts (a) to (d), displays a sequence of consecutive steps of the surgical procedure in a somewhat more schematic presentation. In the view of Figure 14 (a), it can be seen that the gastroscop 80 includes a working channel 84 which can be used to insert surgical instruments through the gastroscop 80 into the stomach 70.

Figure 14 (a) shows the state after the gastroscop 80 has been introduced and moved into the retrograde state defining the Z line, i.e. an area close to the junction of the esophagus 72 and the stomach 70. Moreover, a retractor 86 has already been fixed at a site 88 of the anterior mucosal wall of the stomach 70, about 3 cm below the Z line. In Figure 14, the retractor 86 is represented in a very schematic way, just to illustrate the

principle of the surgical procedure. An actual embodiment of the retractor 86 is explained below. The retractor 86 is designed as a separate instrument and has been introduced through a working channel of the gastroscop 80. According to Figure 14 (a), the retractor 86 has already pulled the stomach wall somewhat inwards.

Figure 14 (b) shows a state after additional traction has been applied to the retractor 86 to form a full thickness transversal fold 89 of stomach wall tissue. Moreover, the stapling instrument 1 has been introduced to the site of the fold 89 through the esophagus 72 alongside the exterior wall of the gastroscop 80, using the gastroscop 80 as guide. Under retrograde view, the staple fastening assembly 6 of the stapling instrument 1, with the anvil 20 and the cartridge 10 in a spaced state, is positioned at the fold 89 such that the fold 89 lies in the gap between the anvil 20 and the cartridge 10.

Now the anvil 20 is moved towards the cartridge 10 by turning knob 9 until both parts of the fold 89 touch each other but are not squeezed too much. The optimal gap distance for this stage can be preadjusted at the handle 2 (e.g. by means of a stop to block further rotation of knob 9).

In the state shown in Figure 14 (c), the stapling instrument 1 is "fired" by actuating the trigger 8 and expelling the staples 40 as explained before. The free ends of the staples 40 penetrate both layers of the fold 89 before they are bent by the anvil 20. After extracting the stapling instrument 1, the stapled fold 89 can be checked with the gastroscop 80. Afterwards, the gastroscop is extracted as well.

Figure 14 (d) shows the result of the surgery: a permanent transversal fold 89 below the LES valve. If desired, a similar fold can be created on the posterior wall, just opposite to the fold 89. Before stapling the second fold, the stapling instru-

ment 1 has to be extracted and re-introduced in order to replace the old cartridge 10 with a fresh one containing the required staples.

The fold 89 and, if applicable, the additional fold close off the esophagus 72 and influence the circulation pattern in the stomach 70, such that gastric reflux does not rise into the esophagus 72. On the other hand, food intake is not seriously impeded because the fold(s) yield and do not block the esophagus. Since the esophagus 72 is not constricted in any way, dysphagia cannot occur.

Figure 14 also demonstrates that the shape of the staple fastening assembly 6 and the flexible shaft 4 fit well to the shape of the gastroscop 80. Therefore, the limited cross-sectional area of the esophagus 72 is optimally used.

Figures 15 and 16 display an actual embodiment of a retractor 86, here designated by the reference numeral 90. In its distal end region, the retractor 90 comprises a screw, which is designed as a helical coil 92 having a tip 94. The coil 92 is connected to a base part 96 which is fixed to a flexible retractor shaft 98 made, e.g., from a soft and tightly wound helical spring covered by a flexible plastic sheath. Figures 15 and 16 show the distal end region of the retractor shaft 98 only. The total length of the retractor shaft is sufficient to extend through the esophagus and mouth of the patient such that the retractor 90 can be manually handled via the proximal end of the retractor shaft 98.

Figure 17 illustrates sequential steps of the use of the retractor 90. Figure 17 (a) corresponds to Figure 13 and shows the gastroscop 80 after insertion into the stomach 70 and pointing in retrograde view. Parts (b) to (e) of Figure 17 show the individual steps until the state corresponding to Figure 14 (a) is reached. In part (b), the retractor 90 is moved to the desired

site 88 until the tip 94 of the coil 92 contacts the anterior mucosal wall. Then, the retractor 90 is rotated, part (c), in order to perforate the stomach wall all the way through the serosa. Afterwards, traction is applied, part (d), until a full thickness transversal fold is formed, i.e. the fold 89, part (e). Following these steps, the steps displayed in Figure 14 parts (b) to (d) are performed.

The use of a second embodiment of the surgical system in a surgical procedure for the treatment of gastroesophageal reflux desease is illustrated in Figure 18. This figure, in parts (a) to (l), shows sequential steps of the procedure. The final result, a transversal fold similar to fold 89 above, is displayed in Figure 19.

In the second embodiment of the surgical system, the retractor is integrated in the stapling instrument which is designated by reference numeral 100. The parts of the instrument related to stapling are very similar to the corresponding parts of the stapling instrument 1. For this reason, these parts have the same reference numerals as before (but primed), and they are not explained again. Figure 18 shows the essential parts of the stapling instrument 100, in particular its staple fastening assembly 6' including the essential parts of the retractor. Since the retractor comprises several movable parts which are driven and actuated via force-transmitting devices contained in the flexible shaft of the stapling instrument 100, there are more actuating members for operating the force-tranmitting devices loctated at the handle than in the embodiment described before. A person skilled in the art knows how to achieve the movements and actions of the retractor described below. Generally, the flexible shaft (here 4') can be designed in a similar way as explained by means of Figures 9 to 11, but preferably with more than one channel in the vertebra members in order to accomodate the larger number of force-transmitting devices.

In Figure 18 (a), the stapling instrument 100 lies at the stomach wall 102 (anterior mucosal wall) at the desired site (about 3 cm below the Z line), with the anvil 20' having a small distance to the end face 16' of the cartridge 10'. In part (b) the anvil 20' has been moved to a spaced position.

The retractor, here designated by the reference numeral 110, includes a retractor sheath 112 with a curved end region 114. The retractor sheath 112 is movable, generally in parallel to the longitudinal axis of the staple fastening assembly 6'. In Figure 18 (c) the retractor sheath 112 has been moved in distal direction compared to parts (a) and (b) such that its distal end 115 is in the center region of the space enveloping the anvil 20' and the end face 16' of the cartridge 10'. In Figure 18 (d) part of the cartridge 10' and the staple driving device are shown in longitudinal section, similar to the representation in Figure 12.

In the next step, a curved hollow needle 116 having a piercing tip 117 is driven out of the retractor sheath 112 by means of a hollow and flexible force transmitter 118, part of which is displayed in Figure 18. The proximal area of the force transmitter 118, which extends all the way through the flexible shaft, is not shown in the figures. The piercing tip 117 of the needle 116 perforates the stomach wall at a site 119 all the way to the serosa.

Afterwards, a folded balloon 120 which is mounted on a catheter 122 inside the internal channel of the hollow needle 116 is pushed out of the piercing tip 117 by moving the catheter 122 in distal direction. On the serosa side, the balloon 120 is inflated, the hollow catheter 122 serving as a pressurizing tube. Then, the needle 116 is retracted into the curved end region 114 of the retractor sheath 112, leaving the inflated balloon 120 on the serosa side, as shown in Figure 18 (f).

Now the catheter 122 is retracted, Figure 18 (g). The balloon 120 prevents the catheter 122 from slipping through the piercing site 119. In the next step, the retractor sheath 112 including the catheter 122 and the balloon 120 is moved in proximal direction. Figure 18 (h) shows that a fold 124 of the stomach wall 102 is formed in this way. In Figure 18 (i), the retractor sheath 112 has reached its final position.

In the next step, the anvil 20' is moved in proximal direction as well until it clamps the tissue of the fold 124 to the end face 16' of the cartridge 10'. As in the first embodiment, the desired residual gap between the anvil 20' and the cartridge 10' can be preselected at the handle of the stapling instrument 100. Figure 18 (j) shows this state with the tissue seen in sectional view, whereas in Figure 18 (k) the tissue of the fold 124 is in side view.

Finally, the stapling instrument 100 is fired by driving the staples 40' out of the cartridge 10', as explained in detail with respect to the first embodiment. In Figure 18 (l) a formed staple 40' is shown in sectional view. Additionally, the balloon 120 is deflated and retracted by means of the catheter 122 into the retractor sheath 112, i.e. into the needle 116. Afterwards, the stapling instrument 100 and the gastroscop (not shown in the figures) used to view the procedure can be retracted through the esophagus and the mouth of the patient.

Figure 19 illustrates the result of the surgery: part (a) is a longitudinal representation of the fold 124 including the formed staples 40', and part (b) is a top view onto the fold 124 with four staples 40' arranged along a semi-circular line.

## Claims

1. Surgical system, with
   - a stapling instrument (1; 100) comprising:
     - a flexible shaft device (4) and a handle (2) extending from the shaft device (4) in the proximal end region of the stapling instrument (1; 100),
     - a staple fastening assembly (6; 6') in the distal end region of the stapling instrument (1; 100), the staple fastening assembly (6; 6') including a curved cartridge (10; 10'), which comprises at least one curved open row of staples (40; 40'), and, opposite to the cartridge (10; 10'), a curved anvil (20; 20'), which has a staple forming face (24) and is adapted to cooperate with the cartridge (10, 10') for forming the ends of the staples (40; 40') exiting from the cartridge (10; 10'),
     - wherein optionally the staple fastening assembly (6; 6') is adapted to allow unobstructed access towards concave inner faces of the cartridge (10; 10') and of the anvil (20; 20'),
     - a moving device (9, 26, 28, 47, 50) adapted to move the anvil (20; 20') relatively with respect to the cartridge (10; 10'), essentially in parallel relationship, from a spaced position for positioning tissue therebetween to a closed position for clamping the tissue, and
     - a staple driving device (8, 49, 52, 54, 56) adapted to drive the staples (40; 40') out of the cartridge (10; 10') towards the anvil (20; 20'); and
   - a retractor (90; 110) adapted to draw tissue into the space between the cartridge (10; 10') and the anvil (20; 20'), when the cartridge (10; 10') and the anvil (20; 20') are in the spaced position.

2. Surgical system according to claim 1, characterized in that the staple forming face (24) of the anvil (20; 20') is generally planar and is arranged transversally with respect to

the longitudinal axis of the staple fastening assembly (6; 6').

3. Surgical system according to claim 1 or 2, characterized in that the cartridge (10; 10') and the anvil (20; 20') have a generally arc-like shape in the cross-sectional plane, the arc extending over an angle in the range 90° to 350°.

4. Surgical system according to one of claims 1 to 3, characterized in that the anvil (20; 20') is supported by means of at least one arm (26) extending from an end of the anvil (20; 20') and generally running in parallel to the longitudinal axis of the staple fastening assembly (6; 6').

5. Surgical system according to claim 4, characterized in that the moving device (47, 50) is connected to the arm (26).

6. Surgical system according to one of claims 1 to 5, characterized in that the staple fastening assembly (6; 6') includes a curved holder (12) which is adapted to accomodate the cartridge (10; 10').

7. Surgical system according to claims 5 and 6, characterized in that the holder (12) comprises a guide (28) adapted to slidably guiding the arm (26).

8. Surgical system according to one of claims 1 to 7, characterized in that the distance between the cartridge (10; 10') and the anvil (20; 20') in the closed position is adjustable.

9. Surgical system according to one of claims 1 to 8, characterized in that the staple fastening assembly (6) comprises a retaining pin (30) adapted to move, preferably to slide, between the cartridge (10) and the anvil (20) to align the cartridge (10) and the anvil (20).

10. Surgical system according to claim 9, characterized in that the movement of the retaining pin (30) is actuateable via an actuating member located at the handle (2).

11. Surgical system according to one of claims 1 to 10, characterized in that the staple driving device (8, 49, 52, 54, 56) is adapted to simultaneously drive the staples (40; 40') out of the cartridge (10; 10') towards the anvil (20; 20').

12. Surgical system according to one of claims 1 to 11, characterized in that the flexible shaft device (4; 4') comprises a plurality of vertebra members (60), which are longitudinally arranged and are surrounded by a flexible sheath (64).

13. Surgical system according to claim 12, characterized in that the each of the vertebra members (60) has at least one opening, the openings of the longitudinally arranged vertebra members (60) forming at least one channel (62) adapted to accomodate force transmitting devices (47, 49) for transmitting forces from actuating members (8, 9) located at the handle (2) to the staple fastening assembly (6; 6').

14. Surgical system according to claim 13, characterized in that the force transmitting devices include a flexible band (47) associated to the moving device (9, 26, 28, 47, 50) and a flexible band (49) associated to the staple driving device (8, 49, 52, 54, 56).

15. Surgical system according to one of claims 1 to 14, characterized in that the staple fastening assembly is removably mounted in the distal end region of the flexible shaft device.

16. Surgical system according to one of claims 1 to 15, characterized in that the cartridge (10; 10') is replaceable.

17. Surgical system according to one of claims 1 to 16, characterized in that the retractor (90) is an instrument separate from the stapling instrument (1).

18. Surgical system according to one of claims 1 to 16, characterized in that the retractor (110) is integrated in the stapling instrument (100).

19. Surgical system according to claim 17, characterized in that the retractor (90) comprises a screw (92) which is adapted to pierce and to be screwed into tissue and which is mounted at one end of a flexible retractor shaft (98).

20. Surgical system according to claim 19, characterized in that the screw (92) is designed as a coil.

21. Surgical system according to claim 18, characterized in that the retractor (110) comprises a hollow needle (116) with an internal channel and an expandable balloon (120), which is adapted to be pushed out of the piercing tip (117) of the needle (116) via the channel.

22. Surgical system according to claim 21, characterized in that the needle (116) is designed as a curved needle.

23. Surgical system according to claim 21 or 22, characterized in that the needle (116) is slidably mounted in a retractor sheath (112) having a proximal end and a distal end (115), wherein the needle (116) can be moved out of the distal end region of the retractor sheath (112) by means of a force transmitter (118) operated via the proximal end region of the retractor sheath (112).

24. Surgical system according to claim 23, characterized in that the retractor sheath (112) is movable, generally in parallel

to the longitudinal axis of the staple fastening assembly (6').

25. Surgical system according to one of claims 21 to 24, characterized in that the balloon (120) is mounted on a catheter (122).

26. Surgical system according to one of claims 1 to 25, further comprising an endoscope (80), which preferably has a working channel (84).

27. Surgical system according to claim 26, characterized in that the endoscope (80) is a steerable gastroscope adapted to be inserted through the esophagus (72) as far as into the stomach (70).

28. Stapling instrument (1) of the surgical system according to claim 17, 19 or 20.

29. Retractor (90) of the surgical system according to claim 17, 19 or 20.

30. Staple fastening assembly (6; 6') of the surgical system according to one of claims 1 to 27.

31. Cartridge (10; 10'), which is adapted to the stapling instrument (1; 100) of the surgical system according to claim 16.

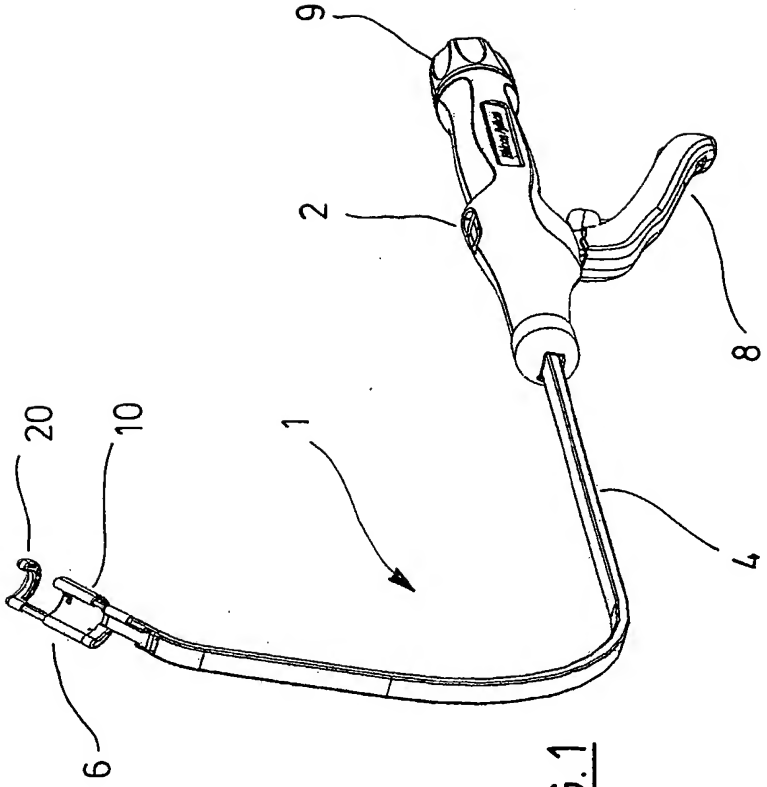



FIG.1




FIG.2

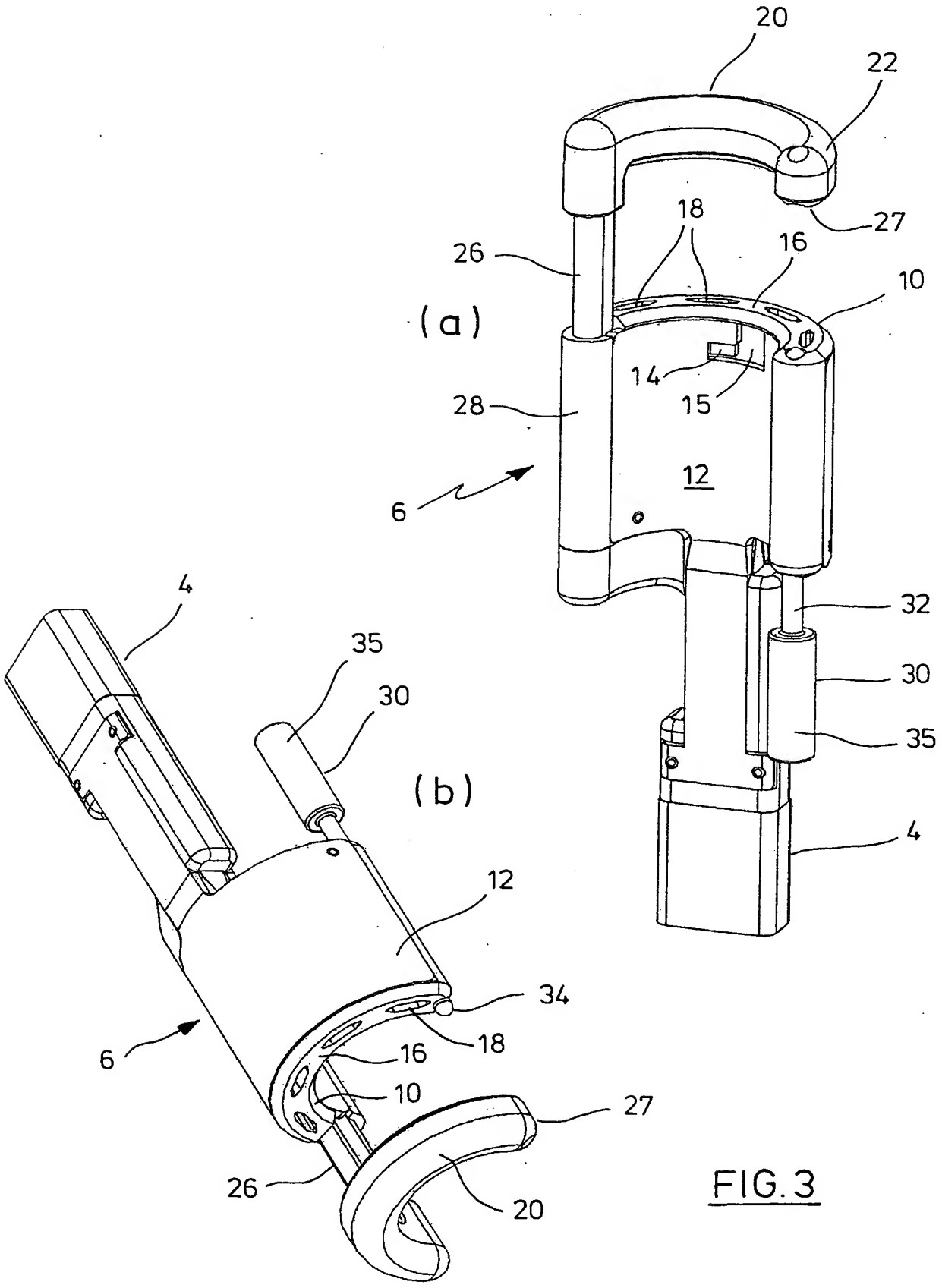

20
22
27
18
16
26
10
(a)
14
15
28
12
6
32
30
35
4
4
35
30
(b)
12
34
18
16
6
10
27
26
20

FIG.3

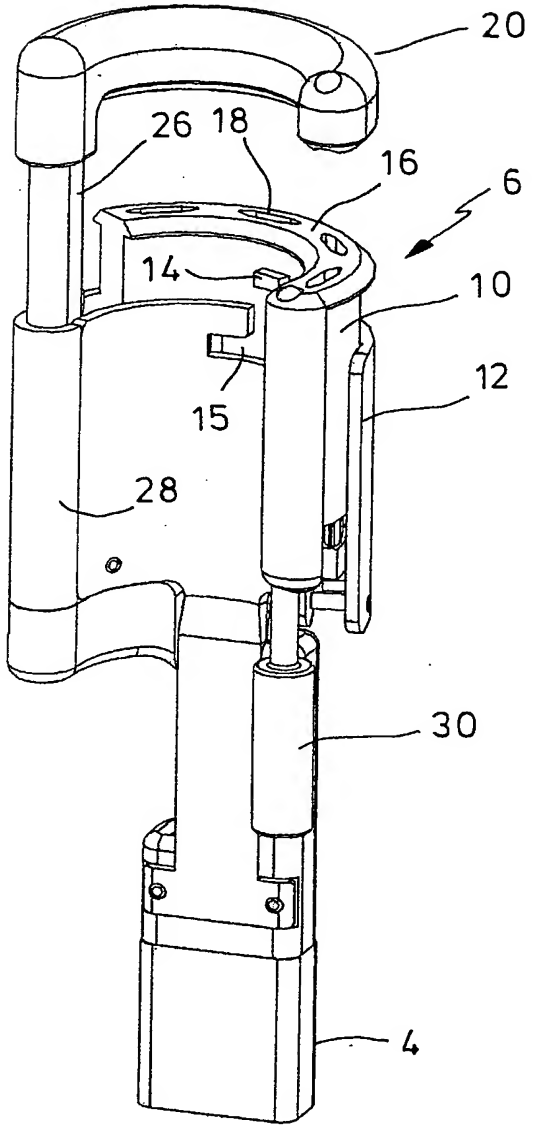



FIG.4

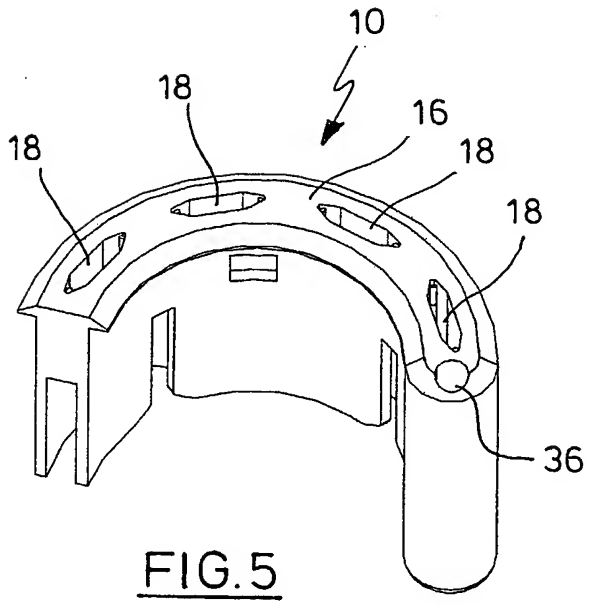



FIG.5

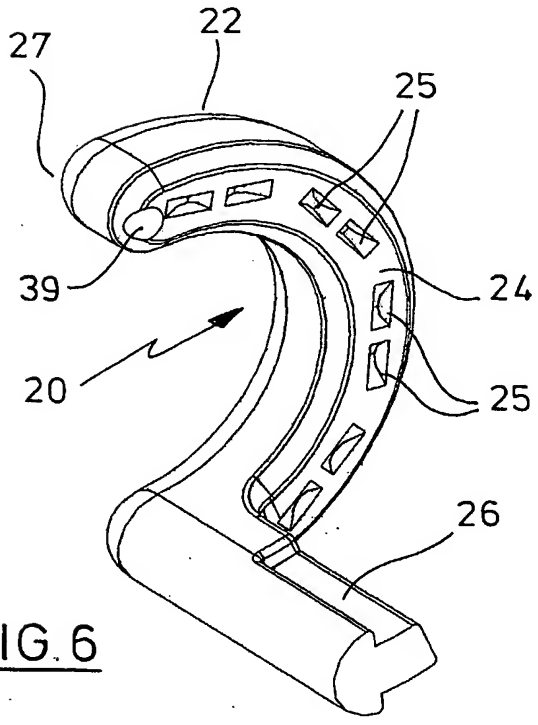



FIG.6

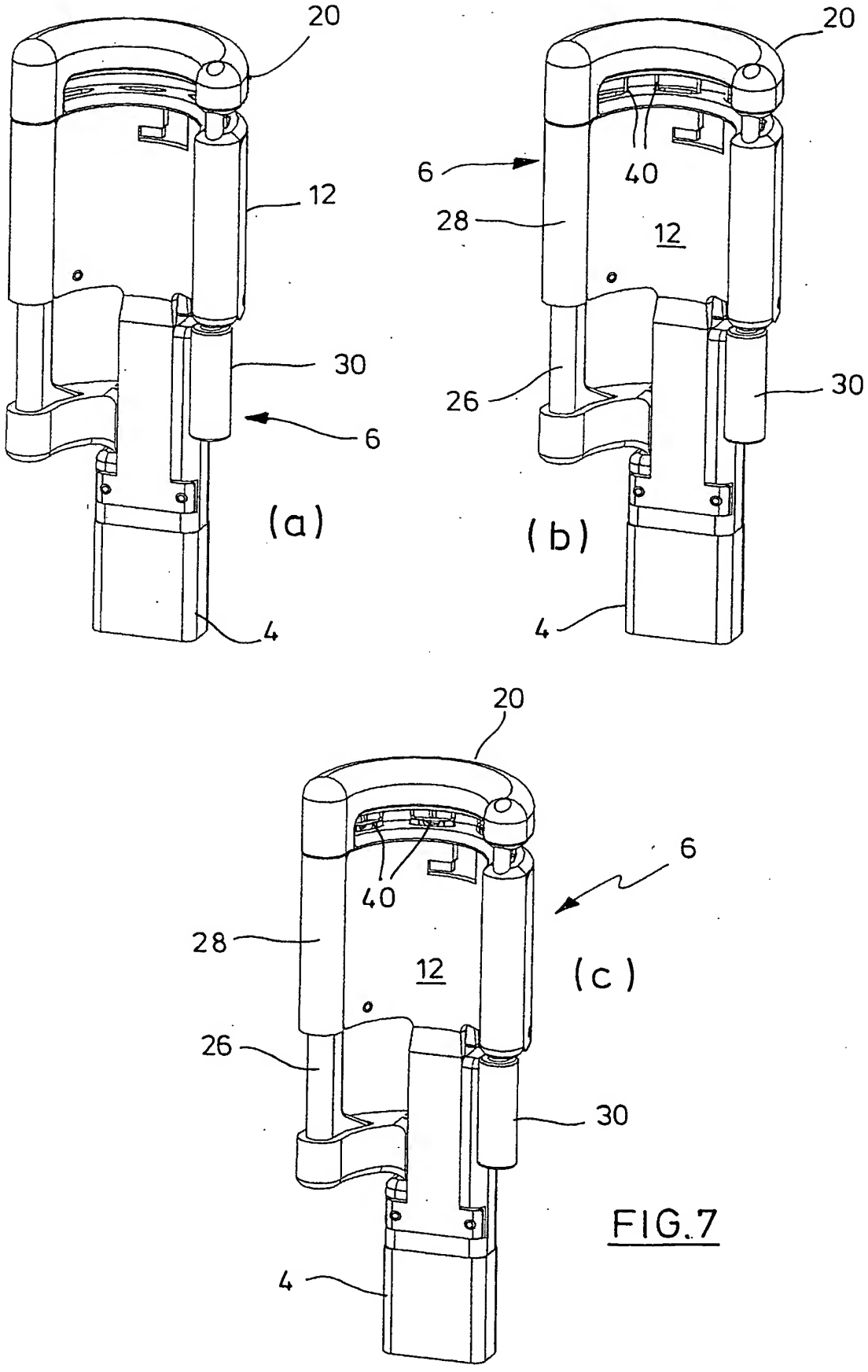



FIG.7

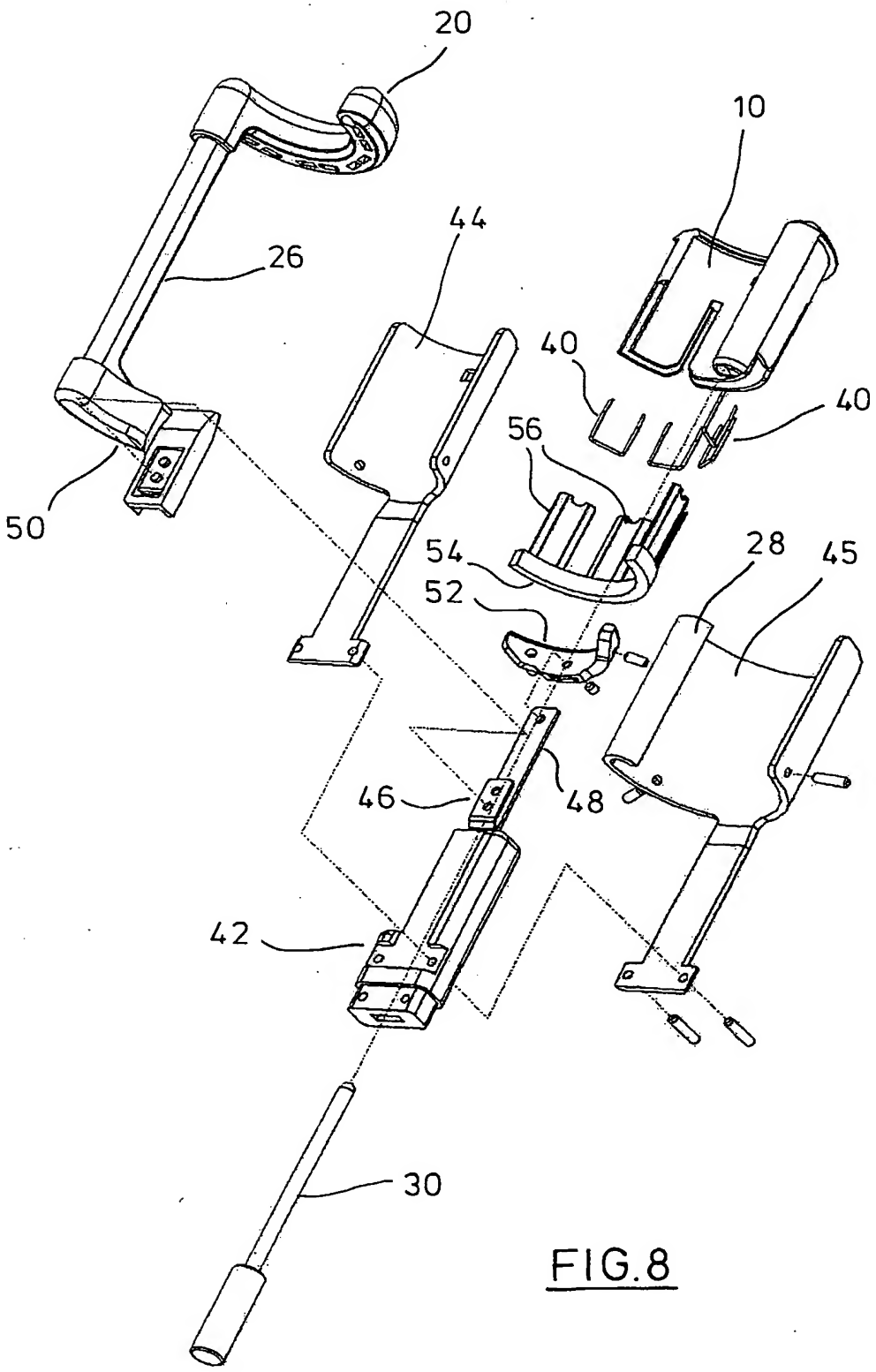



FIG.8

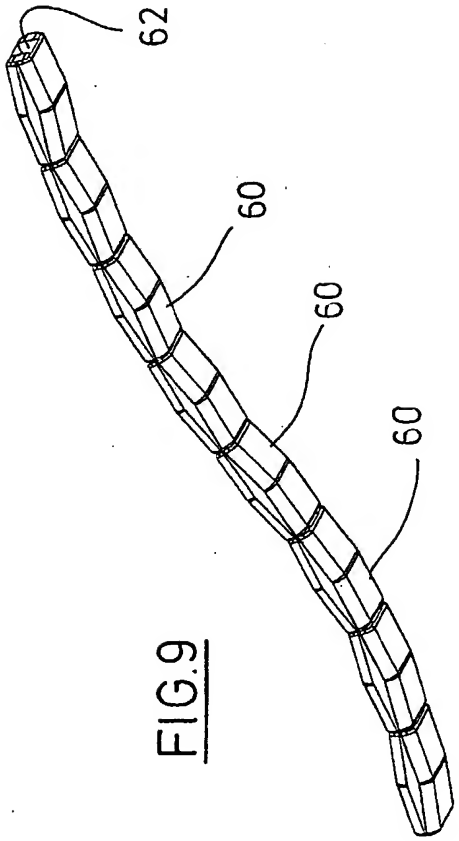



FIG.9

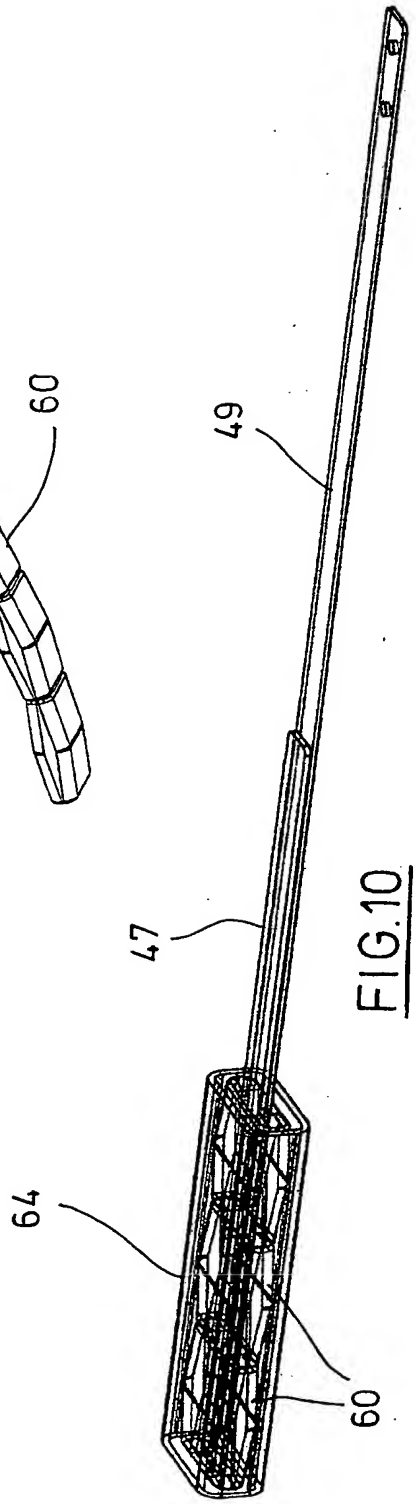



FIG.10

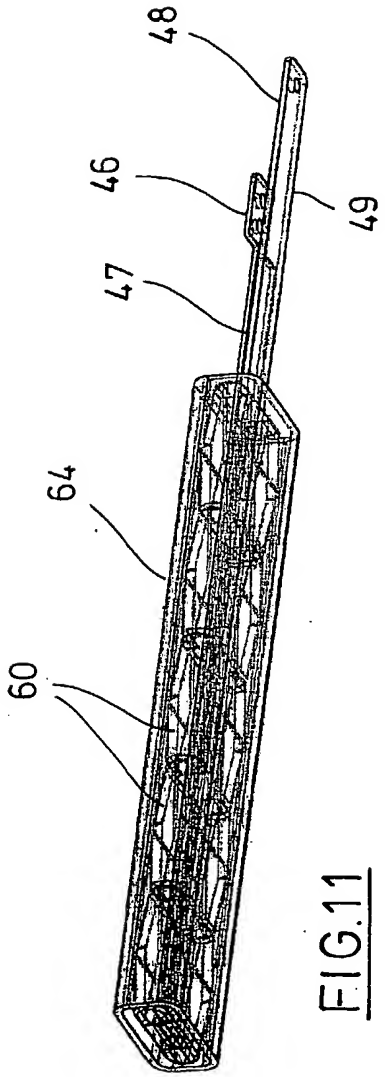



FIG.11

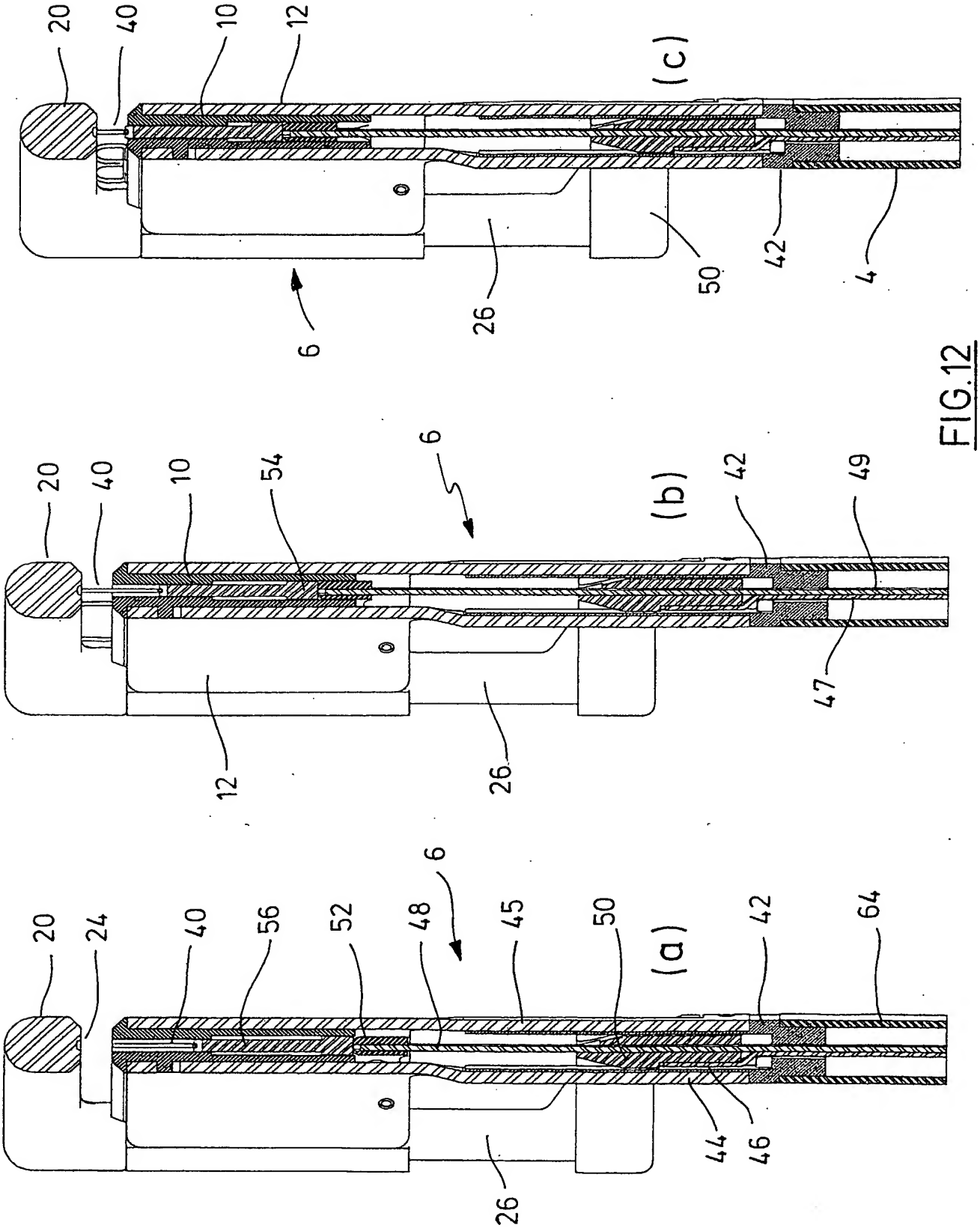

20
40
10
12
(c)
6
26
50
42
4
20
40
10
54
6
(b)
42
49
12
26
47
20
24
40
56
52
48
6
45
50
(a)
42
64
26
44
46

FIG.12

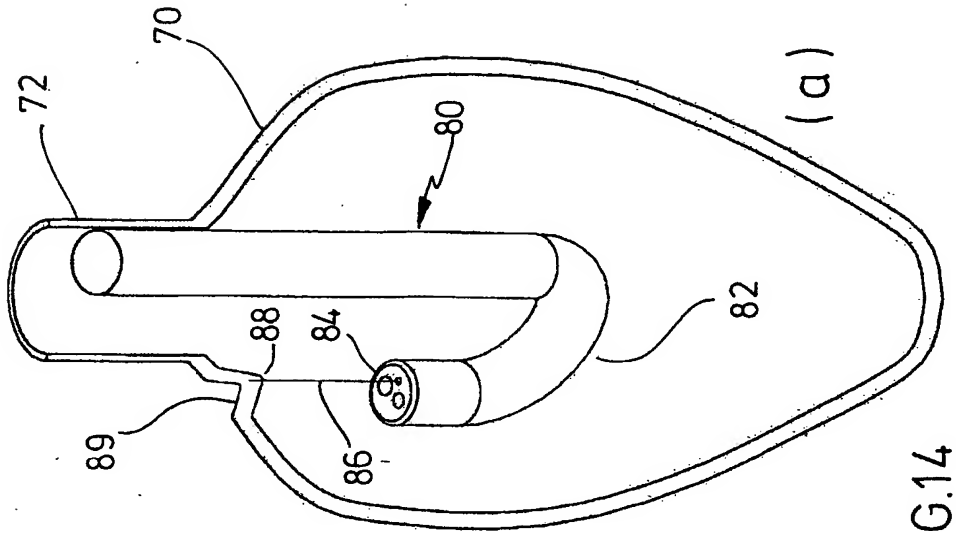



FIG.14

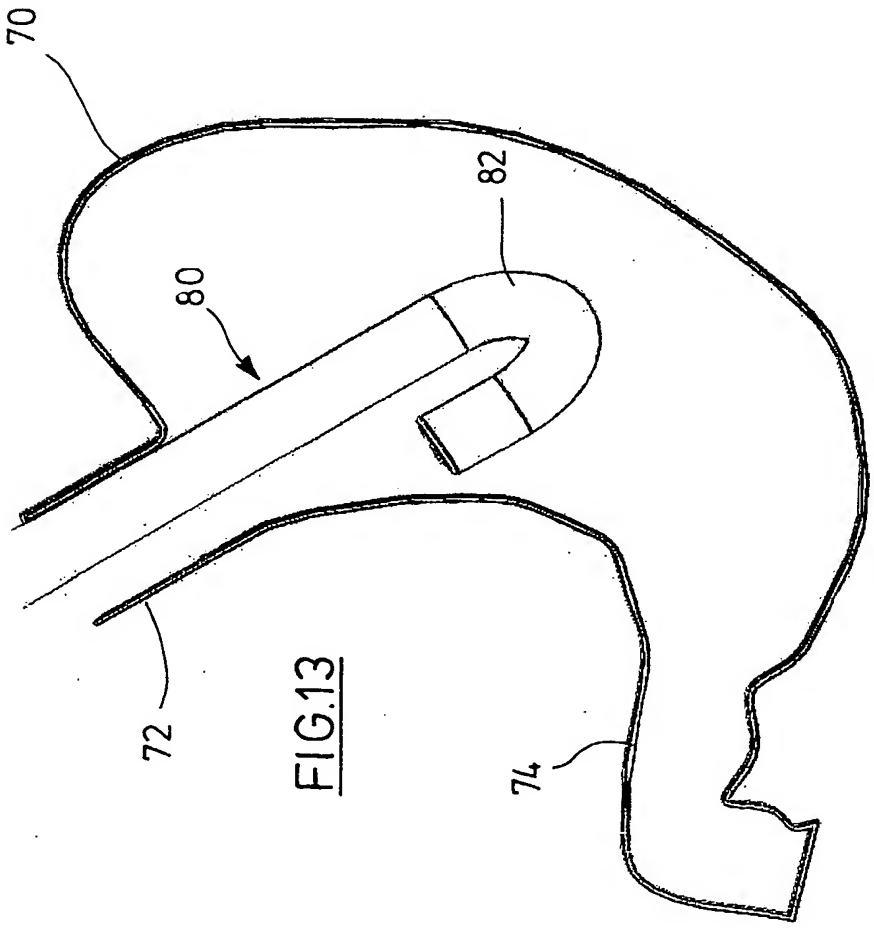



FIG.13

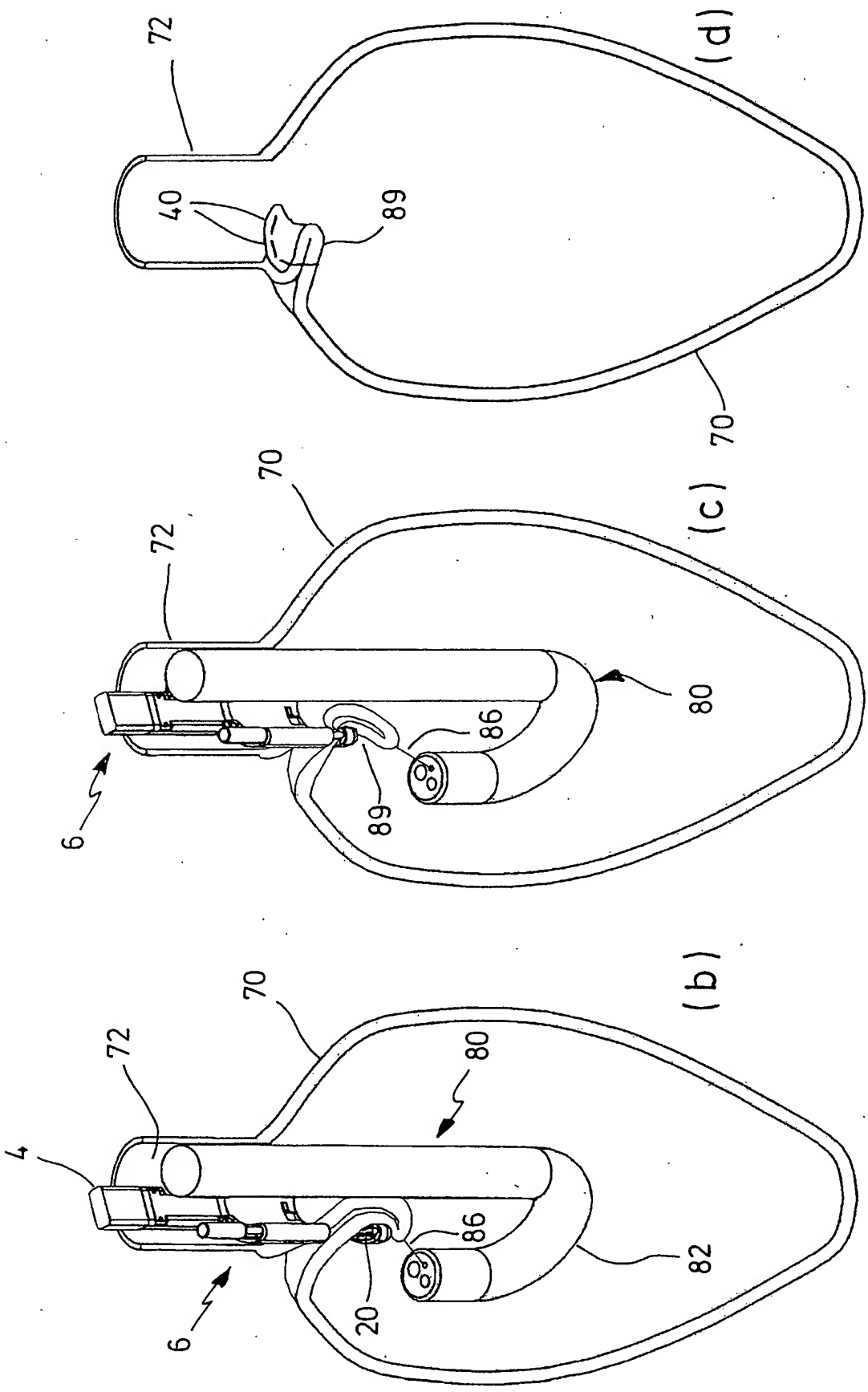



FIG.14

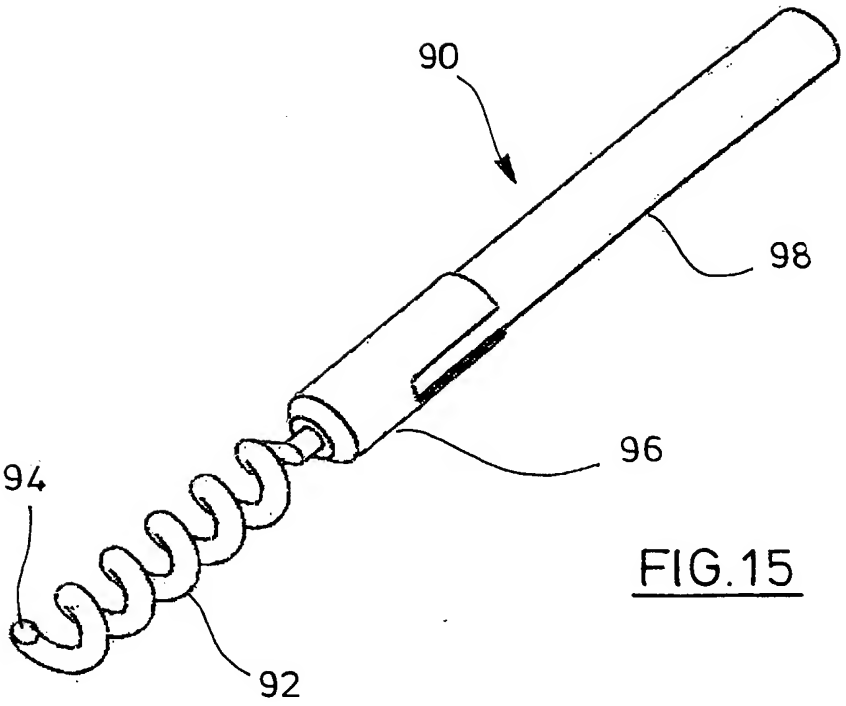



FIG.15

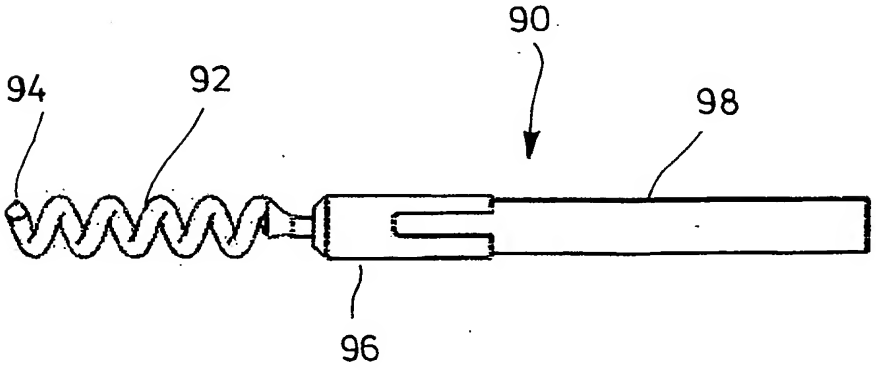



FIG.16

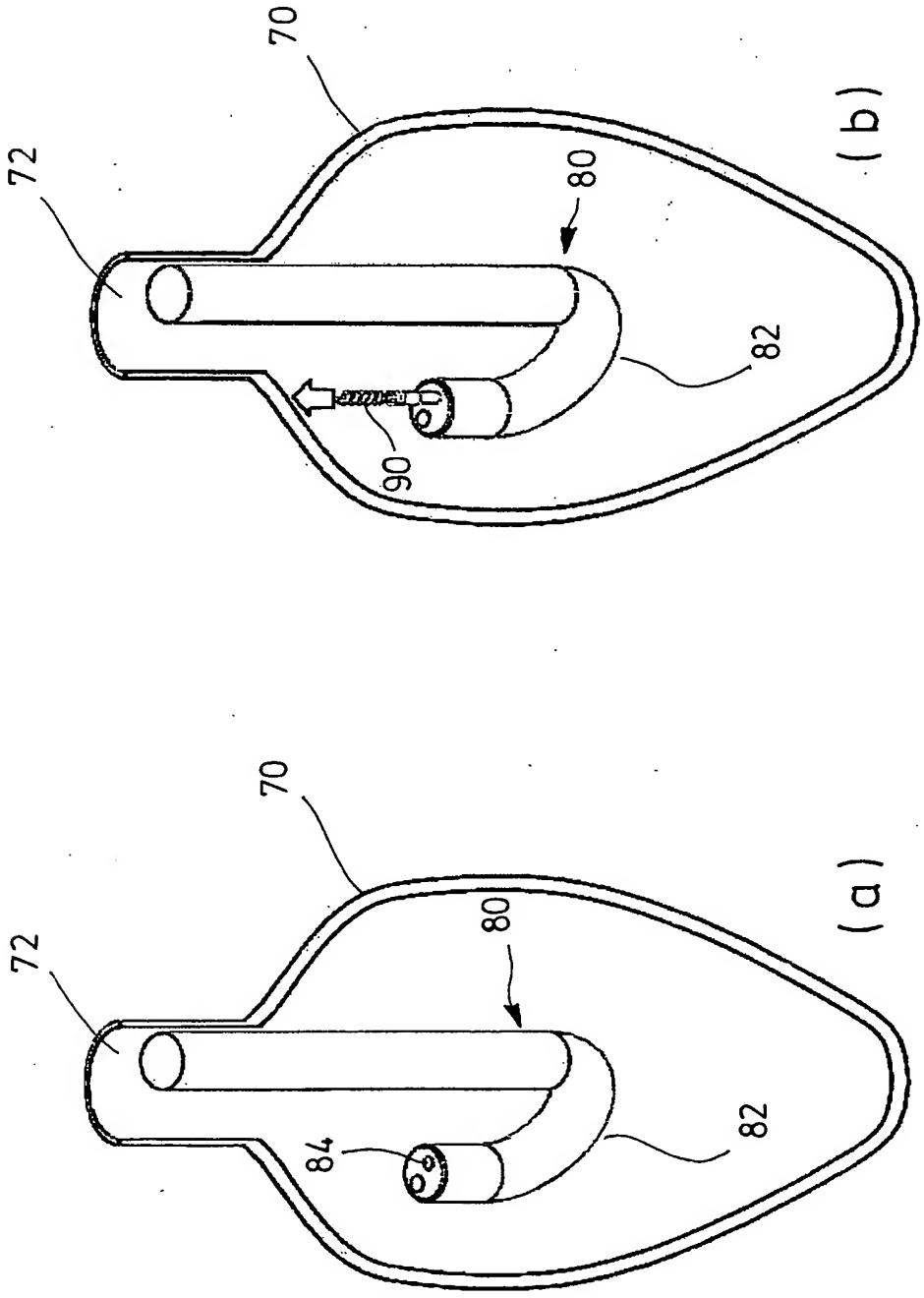



FIG.17

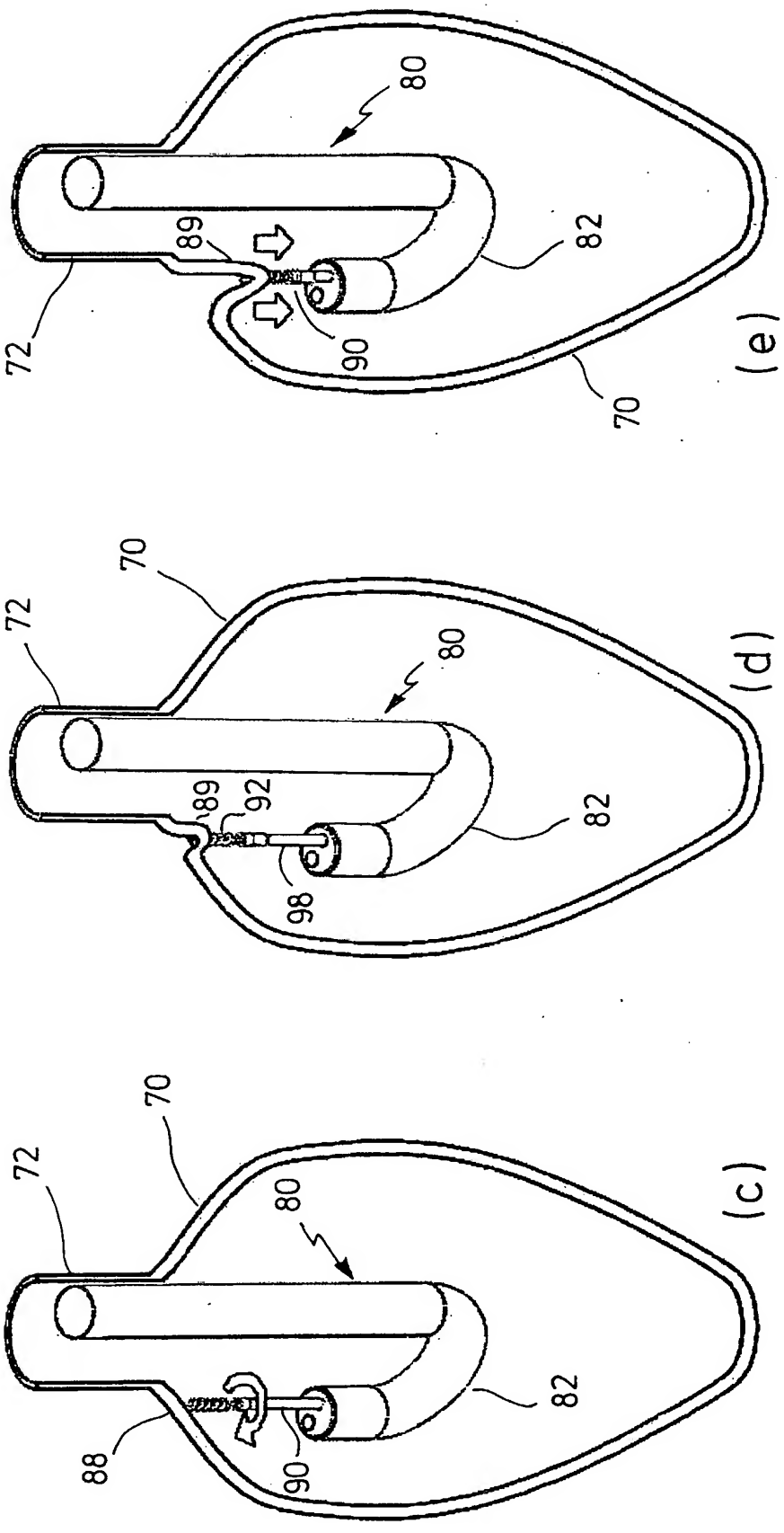



FIG.17

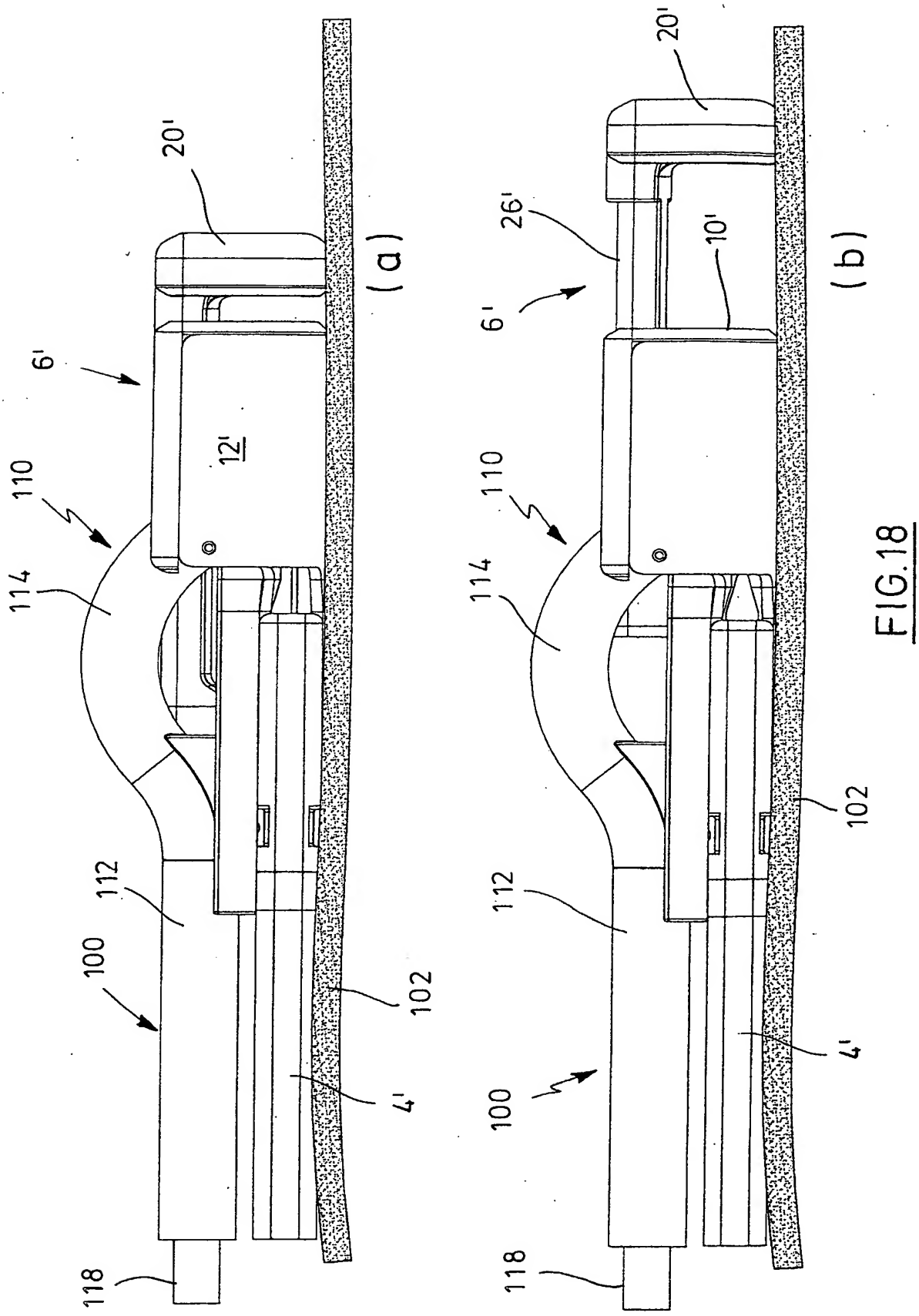

(a)
20'
6'
12'
110
114
112
100
102
4'
118
(b)
20'
26'
10'
6'
110
114
102
112
4'
100
118

FIG.18

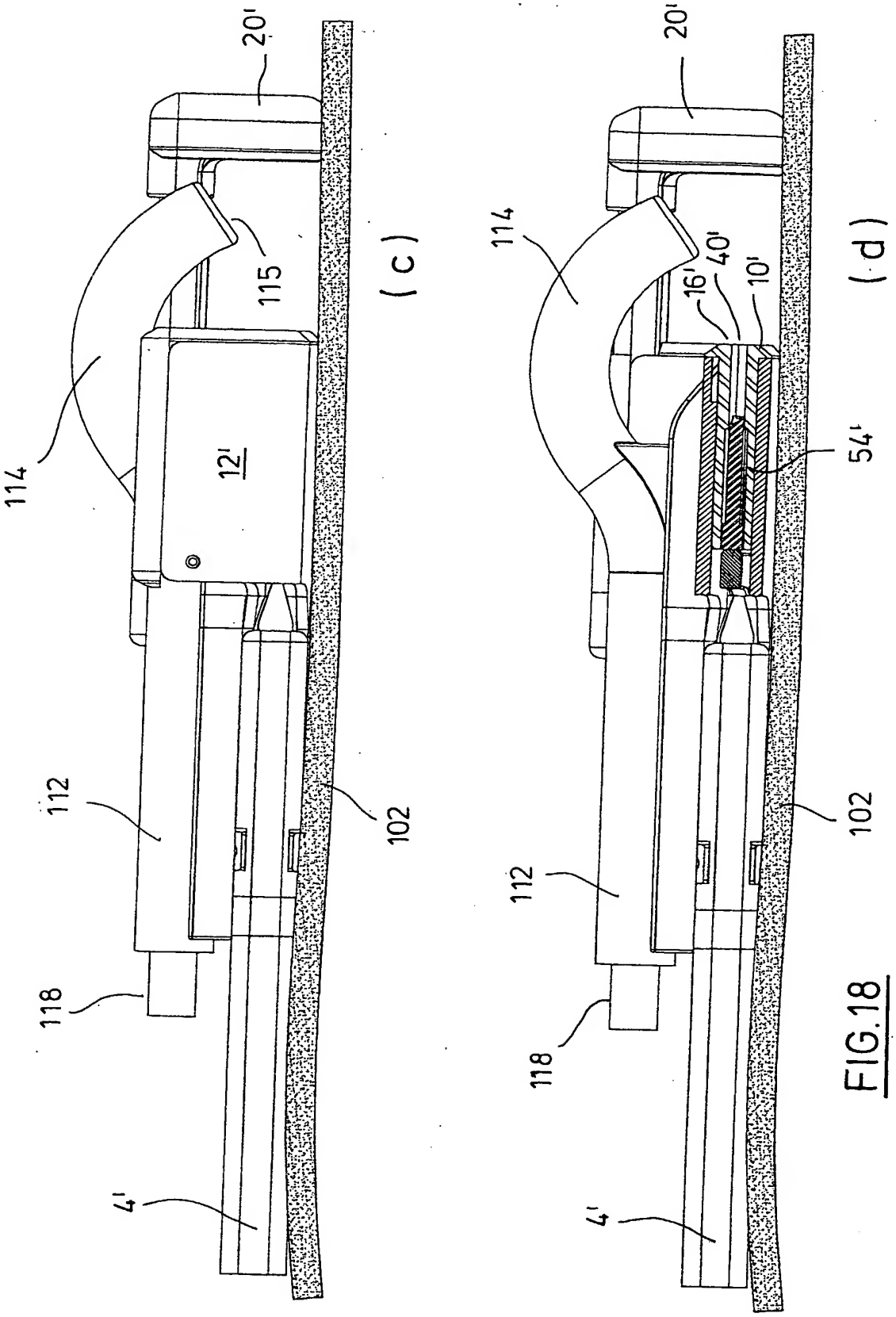



FIG.18

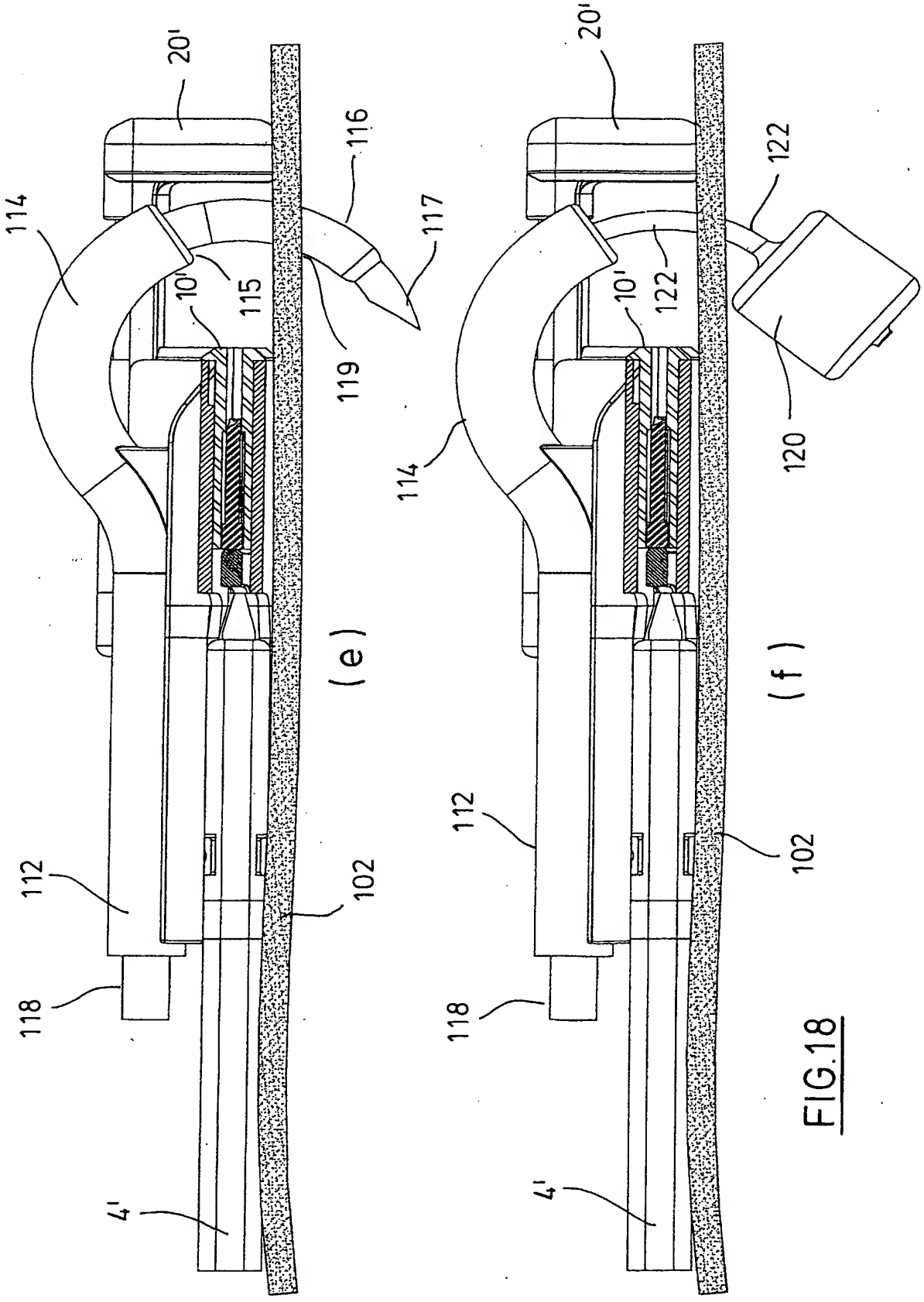
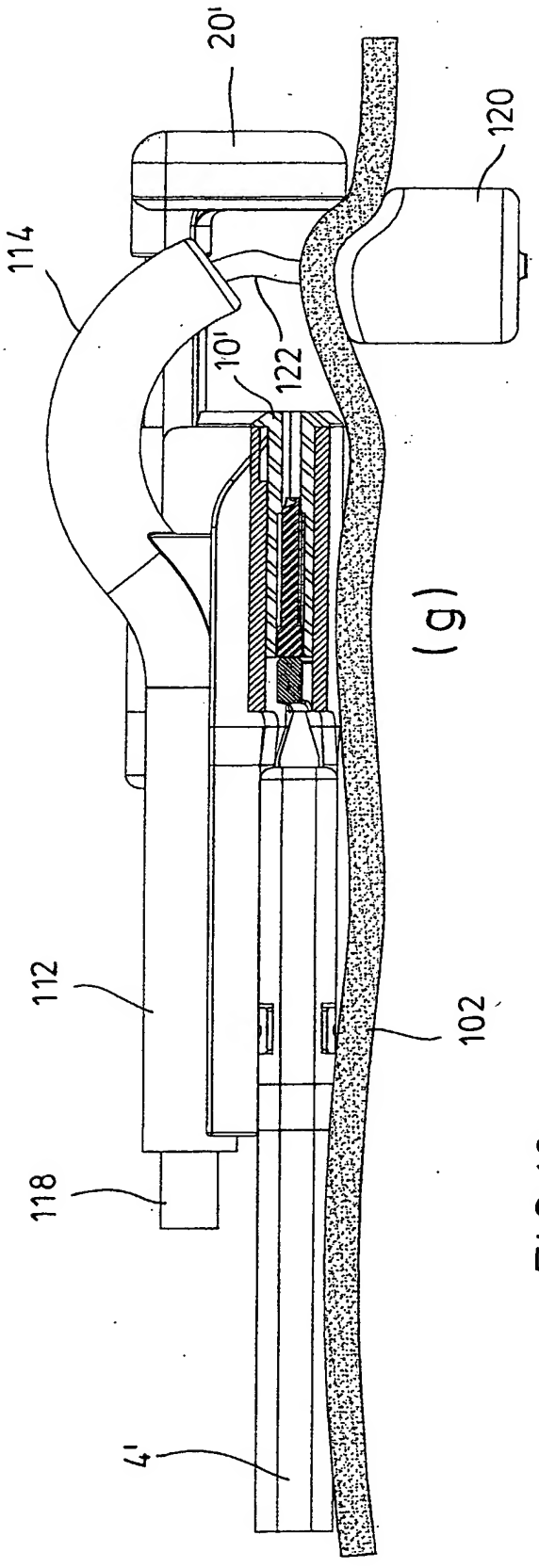

20'
116
114
117
10'
115
119
112
102
118
4'
(e)
20'
122
114
10'
122
120
112
102
118
4'
(f)

FIG.18



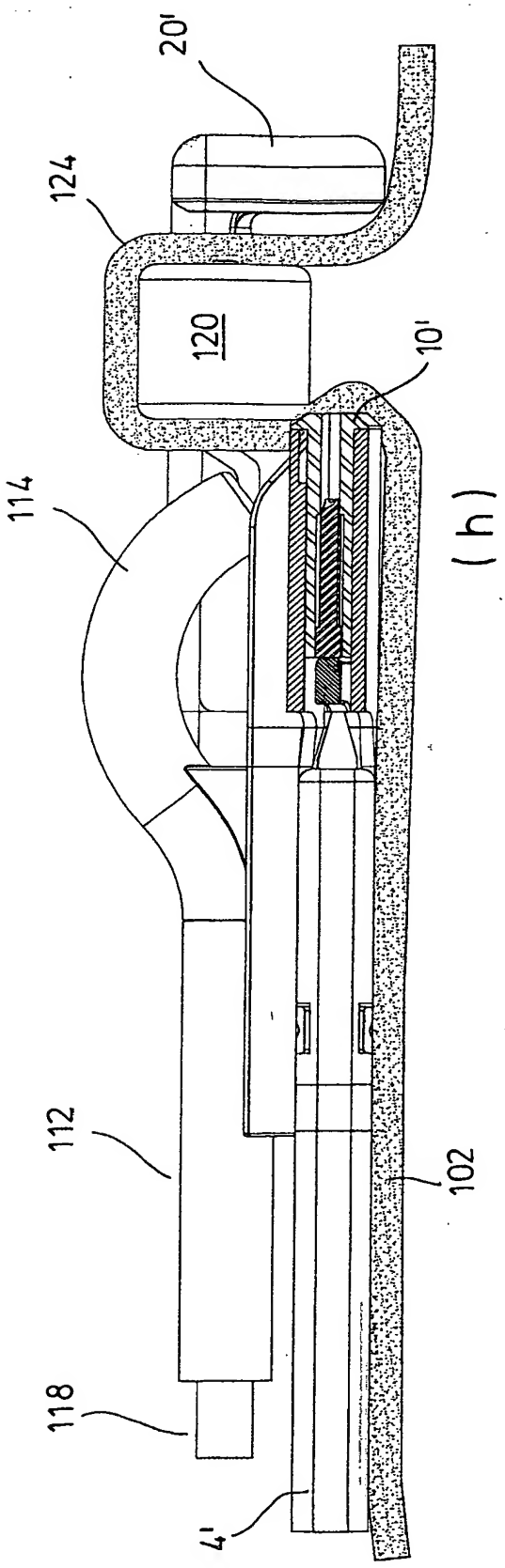
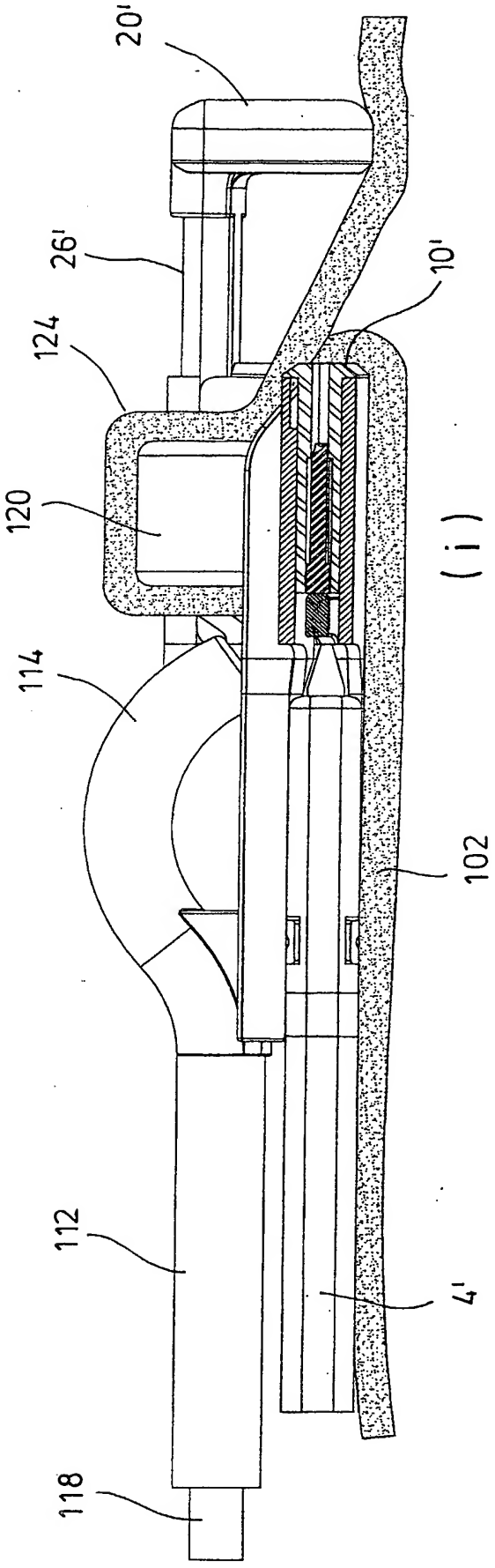




FIG.18


20'
26'
10'
124
120
114
102
112
4'
118
( i )

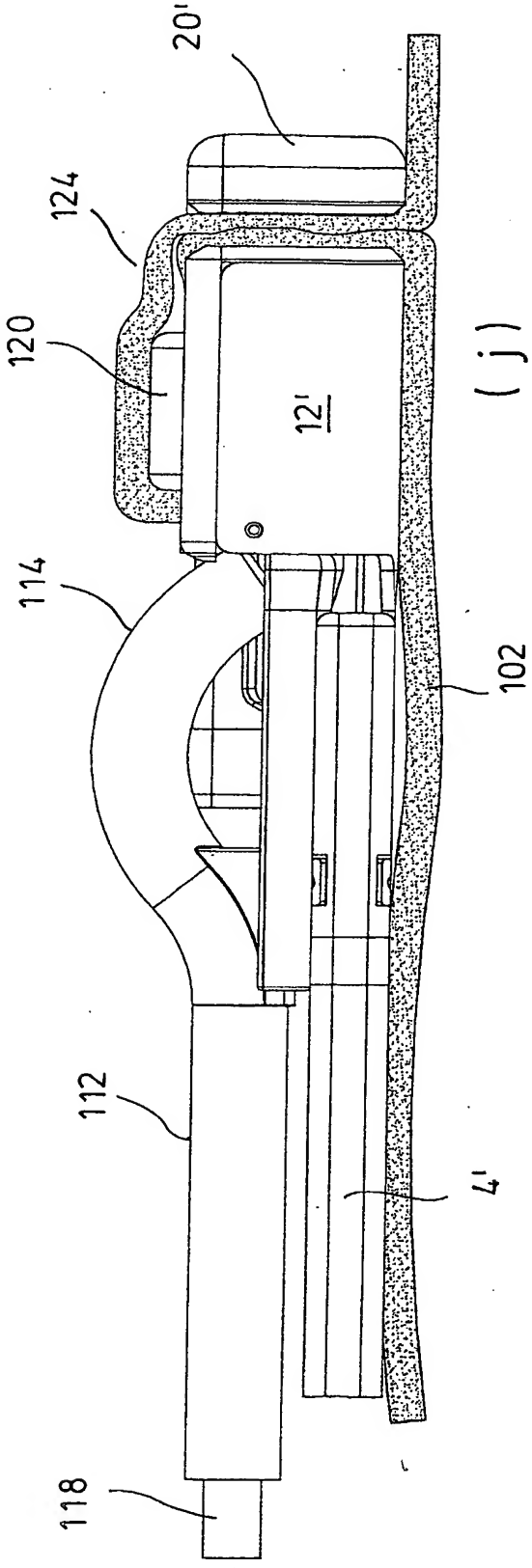
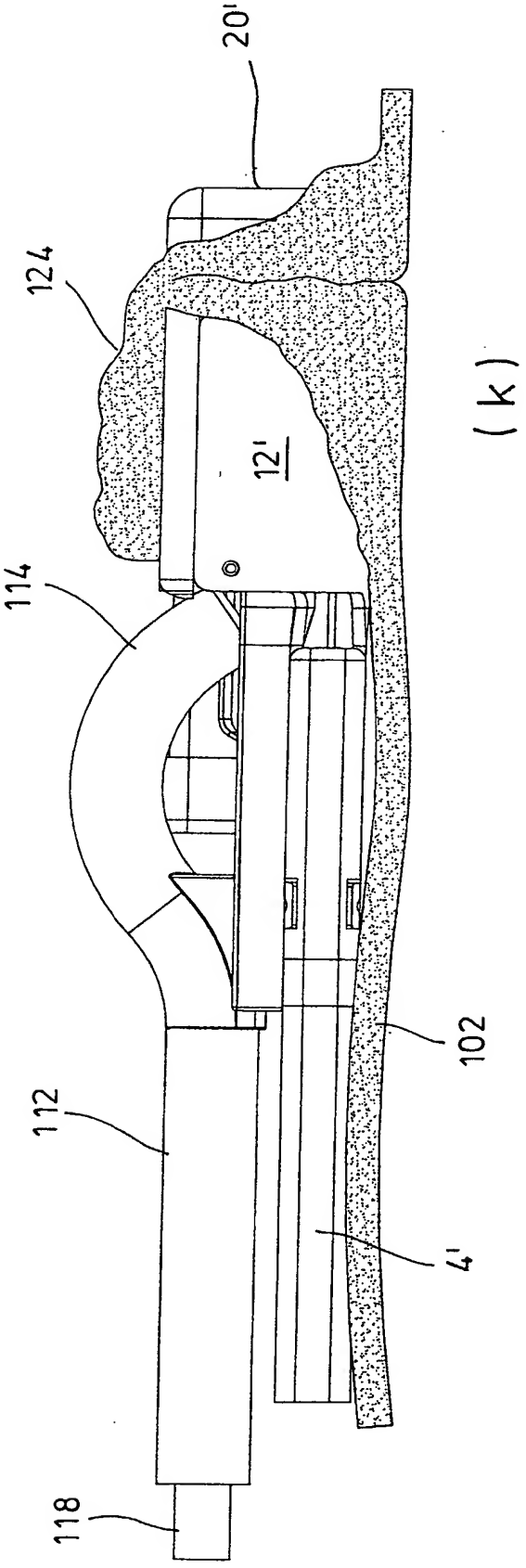

20'
124
120
12'
114
102
112
4'
118
( j )

FIG.18



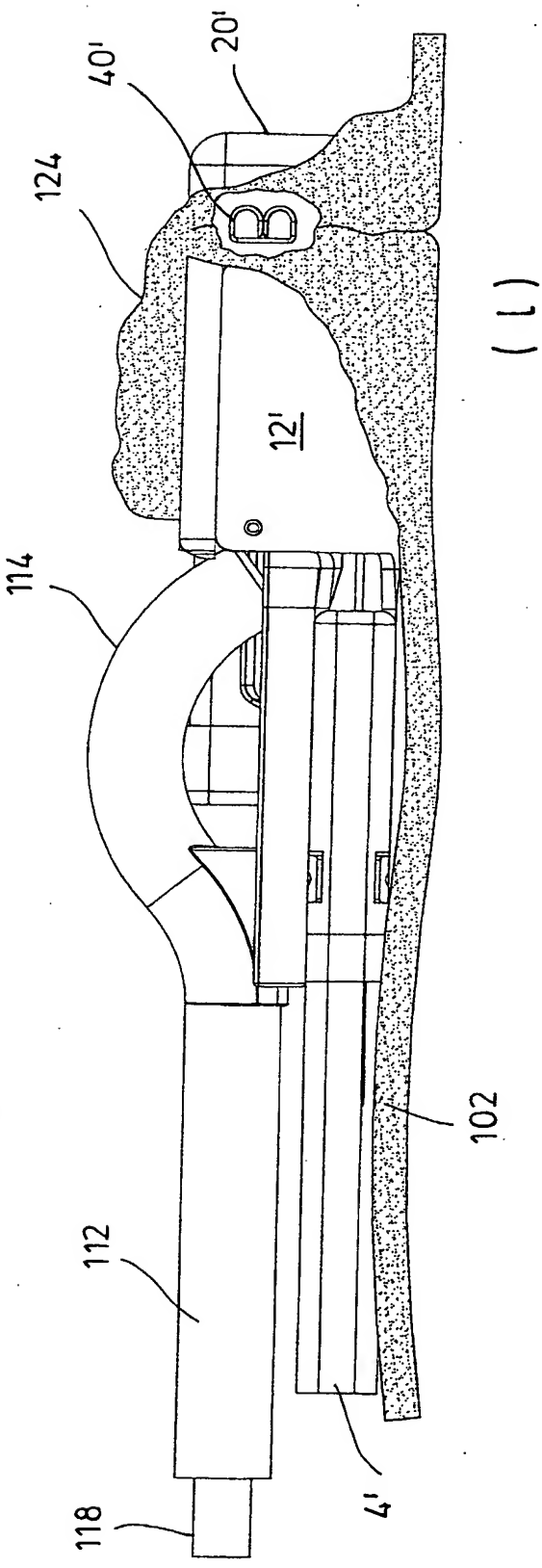




FIG.18

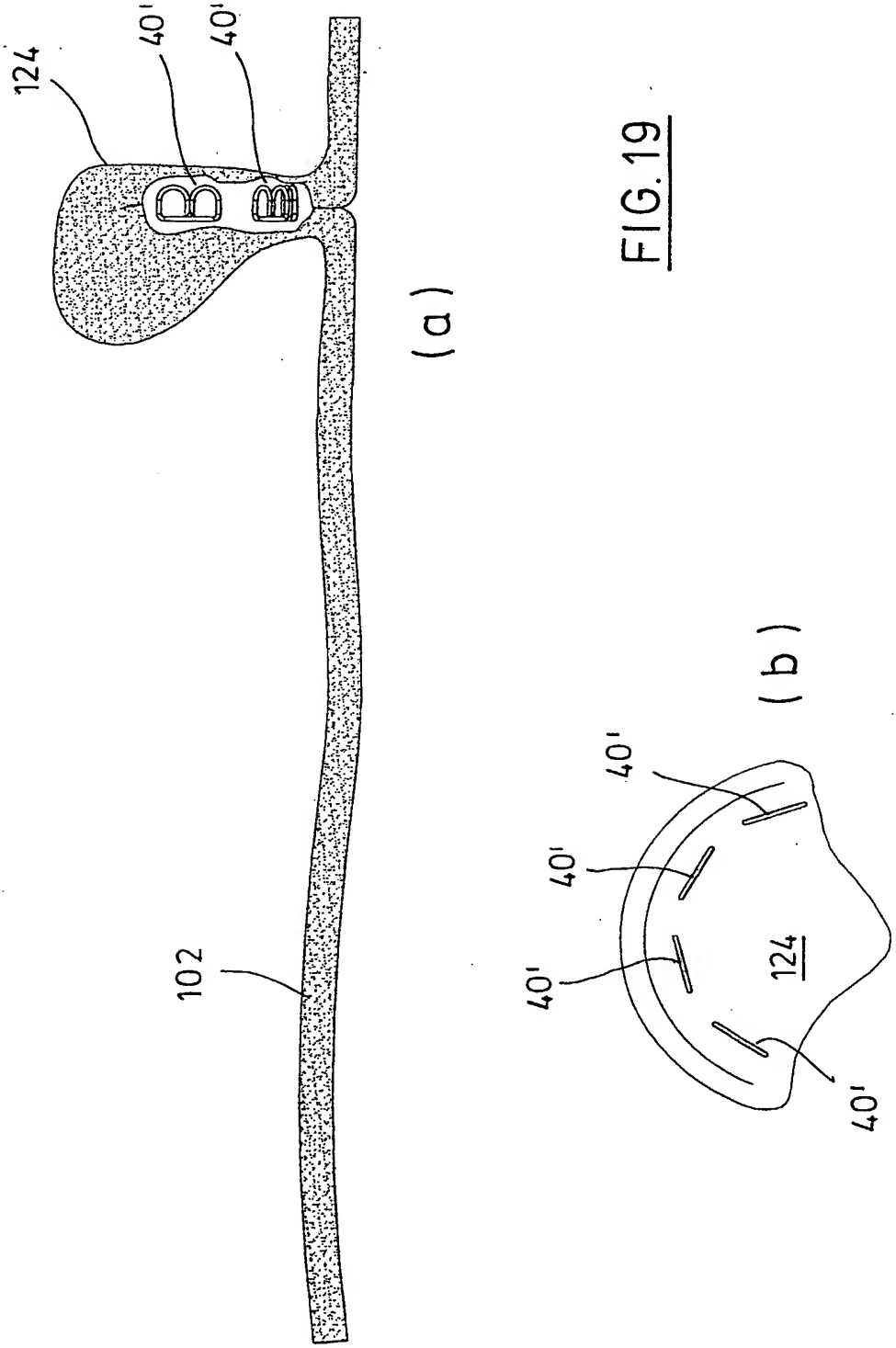



FIG.19

# INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 03/06352

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/072 A61B17/115

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X<br>Y | US 6 119 913 A (MAIN LAUREN O ET AL)<br>19 September 2000 (2000-09-19)<br>column 6, line 16 -column 8, line 27<br>column 9, line 6 - line 32<br>figures 1-4,9A,10,11<br>--- | 1-31<br>17-20 |
| Y | US 6 494 888 B1 (CRUZ AMOS G ET AL)<br>17 December 2002 (2002-12-17)<br>column 4, line 7 - line 42<br>figures 1,3D<br>--- | 17-20 |
| A | WO 01 91646 A (BILOTTI FEDERICO ;ETHICON ENDO SURGERY EUROP GMB (DE); LONGO ANTON)<br>6 December 2001 (2001-12-06)<br>cited in the application<br>page 11, line 33 -page 13, line 17<br>figures 1-4<br>---<br>-/-- | 1 |

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 16 February 2004 | 23/02/2004 |

| Name and mailing address of the ISA | Authorized officer |
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| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax: (+31-70) 340-3016 | Compos, F |

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication,where appropriate, of the relevant passages | Relevant to claim No. |
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| A | US 6 139 563 A (WILLIAMS DONALD B ET AL) 31 October 2000 (2000-10-31) column 5, line 42 - line 59 figures 7C-7E | 12-14 |
| A | US 6 371 943 B1 (WHITCAVITCH BRUCE B ET AL) 16 April 2002 (2002-04-16) column 4, line 63 -column 6, line 26 figures 3,4 | 21-25 |

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